Dual-Use Education Concerns in Biotechnology
Pakistani Perspective

"I am one of those who think like Nobel, that humanity will draw more good than evil from new discoveries"

Marie Curie
Nobel Laureate 1911

Editor
Zabta Khan Shinwari

Department of Biotechnology, Quaid-i-Azam University
and
Pakistan Academy of Sciences

QUAID-I-AZAM UNIVERSITY

iap
the global network of science academies

PAKISTAN ACADEMY OF SCIENCES
MDCCCCLIII

Dual-Use Education Concerns in Biotechnology
Pakistani Perspective

Editor
Zabta Khan Shinwari

QUAID-I-AZAM UNIVERSITY

iap
the global network of science academies

PAKISTAN ACADEMY OF SCIENCES

unicri
United Nations Interregional Crime and Justice Research Institute

CBRN Centres of Excellence
An initiative of the European Union

FONDAZIONE ALESSANDRO VOLTA

Collaborators

Quaid-i-Azam University, Islamabad

Pakistan Academy of Sciences

Inter Academy Panel (IAP)

European Union-CBRN CoE

United Nation Integrated Crime and Justice Research Institute

Landau Network Fondazione Volta (LNFV)

ISBN: 978-969-8223-19-9

Composed by: Engr. Adnan Bashir
Printed by: PanGraphics (Ptv) Ltd., Islamabad

"This effort is dedicated to all the innocent souls of Army Public School, Peshawar, Pakistan who sacrificed their lives in a tragic massacre on 16th December, 2014"

Collaborators

Quaid-i-Azam University, Islamabad

Formerly known as University of Islamabad, Quid-i-Azam University (QAU) was established in 1967. The University is regarded as the best seat for higher studies and research in Pakistan because of its high academic standards, with its graduates accepted by universities and research facilities worldwide. The University collaborates with research institutions in the United States, Europe, and South Asia, and publishes more scientific articles than any other university in Pakistan. The University graduates about 2000 students of MSc, M.Phil, and PhD annually. At present, the University has three faculties, i.e., Natural Sciences, Biological Sciences, and Social Sciences, in addition to the Centers of Excellence and Institutes that include Gender Studies, the National Institute of Pakistan Studies, the National Institute of Psychology, the Area Study Center, the Computer Center, and the Taxila Institute of Asian Civilization. (www.qau.edu.pk/)

Pakistan Academy of Sciences

The Pakistan Academy of Sciences (PAS) is a non-governmental and non-political supreme scientific body of distinguished scientists belonging to different parts of the country and coming from diverse scientific backgrounds. The Government of Pakistan has given consultative and advisory status to the Academy "on all problems relating to the development of scientific effort in the country". The PAS works to promote S&T in the country by organizing lectures, seminars and conferences on topics of national importance and on emerging areas of sciences, and by recognizing the scientists having made outstanding contributions in S&T. The Academy also works to bridge the gap in S&T between Pakistan and the scientifically developed countries of the world. (www.paspk.org)

IAP- The Global Network of Science Academies

IAP and its 107 national, regional and global member academies believe that science, scientific knowledge and scientific progress are essential part of human culture and are vital to advance human welfare and wellbeing. They also believe that the scientific method has much to offer in the pursuit of just and fair societies. IAP is committed to making the voice of science heard on issues of crucial importance to the future of humankind. (www.interacademies.net)

European Union - CBRN CoE

The CBRN CoE Initiative is based on the cooperation at regional, national, and international levels to develop a common and coherent CBRN (Chemical, Biological, Radiological and Nuclear) risk mitigation and reduction policy at national and regional level. Risk reduction comprises of prevention, preparedness and post-crisis management. The Initiative addresses the mitigation of and preparedness against risks related to CBRN material and agents. The origin of these risks can be criminal, accidental, or natural. (www.cbrn-coe.eu/AboutCoE.aspx)

United Nation Integrated Crime and Justice Research Institute

UNICRI is a United Nations entity, established in 1967, to support countries across the globe in preventing crime and facilitating criminal justice. UNICRI supports governments and the international community at large in tackling criminal threats to social peace, development and political stability. UNICRI's programs aim to promote national self-reliance and the development of institutional capabilities. To this end, UNICRI provides a one-stop facility offering high-level expertise in crime prevention and criminal justice problems. Technical co-operation is enhanced by the use of action-oriented research to assist in the formulation of improved policies and concrete intervention programs. Institutional and on-the-job training of specialized personnel form an integral part of UNICRI activities. (www.unicri.it/institute/)

Landau Network Fondazione Volta

Landau Network-Fondazione Volta is a non-profit and non-governmental organization operating as a global network of international experts supporting global science cooperation, security, and disarmament. Its programs include research on scientific and technologic cooperation for global peace support, international security, and policy issues; worldwide disarmament of Weapons of Mass Destruction; and water and energy security. LNFV is also the seat of the Executive Secretariat of the International Working Group (IWG), an informal think-tank of experts and officials sharing their personal capacities. (http://landaunetwork.org/)

Preface

The 21st century is believed to be the century of biology due to phenomenal advancements in life sciences, specifically in biotechnology. This perception also has raised challenges of dual-use research concerns. Hence, there are calls for education, engagement and awareness raising regarding biosecurity and the dual-use issues at international forums. These concerns are more important in developing countries like Pakistan. Hence, we felt the need to introduce the readers to the basic concepts like bioethics, bioweapons, biosecurity and biosafety, while explaining the biotechnologies which can potentially be misused for malicious purposes.

An understanding of the assessment, management and mitigation of the risk associated with dual-use of biotechnology and the laws, rules, legislation and regulation pertaining to these aspects is critical for promoting a safe scientific culture in the country. Therefore, this volume also documents results of the awareness raising surveys which were carried out to do gap analyses to judge the level of awareness among practitioners of science about the "Dual-Use Education".

We are indebted to the concerned students of Quaid-i-Azam University, Islamabad for helping us in collecting the gap analysis survey data from various cities of Pakistan.

We acknowledge financial support of the donor agencies, i.e., Inter Academy Panel (IAP), Pakistan Academy of Sciences (PAS), Higher Education Commission, and Landau Network Fondazione Volta (LNFV). Ms. Gail R. Campbell of the Plants for Humanity Foundation and Dr. Abdul Rashid of the Pakistan Academy of Sciences are appreciated for reviewing the book manuscript.

We are also grateful to Vice Chancellor, Quaid-i-Azam University, Dr. Javed Ashraf, and Dean (Faculty of Biological Sciences), Quaid-i-Azam University, Prof. Dr. Wasim Ahmed, for their support and encouragement.

Zabta K. Shinwari

Message

Vice Chancellor, Quaid-i-Azam University, Islamabad

I am pleased to witness this impressive example of wonderful collaboration among the partner institutions, i.e., QAU, PAS, IAP, LNCV, UNICRI and EU-CBRN-CoE, in an emerging area of concern in the pursuit of scientific research.

The Quaid-i-Azam University (QAU) is one of the country's prestigious universities because of its contributions towards science & technology (S&T) by virtue of its highly motivated staff and hardworking students. Based on its performance, it is fair to say that QAU contains the best brains and the cream of the country. Located in the capital city of the country and surrounded by the scenic beauty of Margalla Hills, the University provides an excellent seat for higher education. The QAU has always been at the forefront regarding scientific and technological activities and publishing. I am proud of my team which has worked selflessly to execute this collaborative project.

The QAU has been actively involved in awareness raising campaigns in the form of surveys and national and international conferences and workshops. The team, led by Prof. Dr. Zabta Khan Shinwari – a renowned professional in his own right, has not only introduced a course on Bioethics and Dual-Use Education to the curriculum, but also have surveyed teachers and students from different universities of Pakistan about the knowledge and understanding about the core concepts like dual-use, bioweapons, bioethics, etc. With the work done, now we are among the few universities around the world which ensure safe and responsible conduct of science.

The Faculty at QAU believes in the responsible conduct of science. We believe that our actions as scientists should bring improvements to the society at large. We have not only established the Institutional Biosafety Committee as our legal obligation, but also have established a viable office of Research Innovation and Commercialization that oversees the research conducted at the campus.

The QAU was founded to play an important role in development of the country by introducing high standards of education. Because of its highly motivated faculty, the number of research publications has increased 5-fold from 2001 to 2010, and during the year 2014 the number of publications has reached ~900. The University believes in entrepreneurship and leadership and aims to produce graduates that are job producers and not the seekers. The QAU will continue to excel in the field of education by offering new and innovative learning opportunities in the natural, social, and biological sciences.

I would like to extend my gratitude towards all the partner institutions of this book. I believe that this book will be used as an effective guide by the scientists and professionals who are directly or indirectly associated with Life Sciences and Biotechnology.

Dr. Javed Ashraf

Message

President, Pakistan Academy of Sciences

It is a matter of honor for me to be a part of this volume, which is a brilliant example of productive cooperation; the collaborating institutions as well as the contributors to this book deserve appreciation. The current volume not only explains the basic principles for responsible conduct of science but also introduces the measures that can be taken to mitigate the associated possible risks. Thus, this book provides a well explained dual side of biotechnology and presents suggestions for safe conduct of science, which are extremely important for the coming generation of scientists.

Established in 1953, the Pakistan Academy of Sciences (PAS) is a non-governmental supreme scientific body of distinguished scientists belonging to different parts of the country and coming from diverse scientific backgrounds. The Government of Pakistan has given the consultative and advisory status to the Academy "on all problems relating to the development of scientific effort in the country". The PAS works to promote S&T in the country by organizing lectures, seminars and conferences on topics of national importance and on emerging areas of sciences, and by recognizing the scientists having made outstanding contributions in S&T. The Academy also works to bridge the gap in S&T between Pakistan and the scientifically developed countries of the world.

Biotechnology and life sciences in Pakistan have moved at such a rapid a pace that there is no parallel in the national history. The scientists should be considered as important people for the regulation of scientific subjects related to biotechnology and should play their integral role for biological risk mitigation. In order to play their part, the scientists should be aware of the core concepts of bioethics, bioweapons, biosafety, biosecurity and dual-use education. The present book provides an organized collection of chapters to give information about the biological risk mitigation. The readers are introduced to the core concepts and potential misuse of biotechnology.

The other feature worth mentioning about this volume is the wonderful level of international collaboration among the partners. The purpose of this volume is to improve the understanding of the responsibilities of scientists, code of conduct and national legislations relevant to the dual-use research concerns. Educating the present day young scientists will lead to the firm foundations for the prosperous future of biotechnology in Pakistan.

Finally, I appreciate the good work of the collaborators in publishing this book and the hard work put in by the contributors is praise worthy. I hope that this book will help in enhancing understanding regarding dual-use research concerns among the young scientists as they are the educators of tomorrow.

Dr. Anwar Nasim

Table of Contents

List of Figures

List of Tables

Abbreviations and Acronyms

ASM	American Society of Microbiology
BTF	Biosecurity Task Force
BTWC	Biological and Toxin Weapon Convention
BW	Biological Weapon
CBD	Convention of Biological Diversity
CERA	*Center for Environmental Risk Assessment*
CICB	COMSTECH International Committee on Bioethics
CWC	Chemical Weapons Convention
DURC	Dual-Use Research Concerns
EPA	Environmental Protection Agency
GDP	Gross Domestic Product
GMO	Genetically Modified Organism
HCEC	Healthcare Ethics Committee
HEC	Higher Education Commission
HIV	Human Immunodeficiency Virus
IAP	Inter-Academy Panel
IBC	Institutional Biosafety committee
ICLS	International Council for Life Sciences
ICLS	*International Council for the Life Sciences*
IL	Interleukin
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISO	International Standard Organization
LMO	Living Modified Organisms
LNFV	Landau Network –Fondazione Volta
MoST	Ministry of Science and Technology
NACTA	National Counter Terrorism Authority Act
NBC	National Biosafety Centre National Bioethics Committee
NCB	National Commission on Biotechnology
NCGLS	National Core Group in Life Sciences
NIAB	National Institute of Agriculture Biology
NIBGE	National Institute of Biotechnology and Genetic Engineering
NIH	National Institute of Health
NISP	National Internal Security Policy
NPT	Nuclear Non-Proliferation Treaty
NVL	National Veterinary Laboratory
OECD	Organization for Economic Co-operation and Development
ORI	Office of Research Integrity
PARC	Pakistan Agriculture Research Council
PAS	Pakistan Academy of Sciences
PBSA	Pakistan Biological Safety Association
PSDP	Public Sector Development Projects
QAU	Quaid-i-Azam University
RCS	Responsible Conduct of Science
REC	Research Ethics Committee
SARS	Severe Acute Respiratory Syndrome
SECDIV	Strategic Export Control Division
SPICE	Smallpox Inhibitor of Complement Enzymes
SPSA	Sanitary and Phytosanitary Agreement
TB	Tuberculosis
UNSC	United Nations Security Council
USAMRIID	US Army Medical Research Institute of Infectious Diseases
WHO	World Health Organization
WMD	Weapon of Mass Destruction
WTO	World Trade Organization

Chapter 1

Introduction to the Core Concepts of Dual-Use Research in Biotechnology

Ali Talha Khalil[1], and Sohail Ahmad Jan[2]

Department of Biotechnology, Quaid-i-Azam University, Islamabad
[1]talhakhalil.qau@gmail.com, [2]sjan.parc@gmail.com

.

The quest for a brighter horizon is ongoing and moving at an ever-increasing speed. It can be inferred that the society is unprepared for it. The development of civilization is classified on the human timeline in five major periods that include the hunter and gatherer age, the agricultural age, the industrial age, the information age, and the age of wisdom (1). At the beginning of civilization, in addition to tending to other aspects of survival, humans would have focused mainly on how to hunt, gather, and store food for themselves and their families. Gradually, humans developed agriculture: humans could not only hunt and gather food but could also now grow crops for their sustenance. Millennia passed and human beings began to flourish in the industrial age. Eventually, humans felt the need to extend themselves into other parts of the world in order to expand their industrial growth and economy. After that, the human race entered the age of information technology and information sharing. Beginning in the modern era, mankind has entered the age of wisdom. Currently, we are in the age of wisdom in which every new discovery can have extraordinary importance and value for generations to come. The role of scientists has become both essential and pivotal in the present age. As new ideas are discovered and developed, scientists are capable of profoundly changing the lives of all human beings.

From the beginning of civilization, there have been discoveries and inventions that transformed the entire social and political circumstances of human beings. Dramatic events, clearly visible on the timeline of history, changed human life, behavior and ways of thinking. Arguably, that's why we are living in the so-called "global village".

Periods of scientific development such as "the physics revolution" that occurred after Albert Einstein's 19th century landmark equation of mass-energy conversion ($E = mc^2$) caused the scientific community to conclude that such knowledge could have both good and bad consequences. For example, atomic fission chain-reactions can be used to create energy but can also be used to create hostile technologies such as the atomic bomb. The atomic bombs "Little Boy" and "Fat Man" dropped on Japan during World War II resulted in a holocaust on Hiroshima and Nagasaki. Since the invention of atomic bomb, the human race has continuously lived under the overwhelming threat of total annihilation. The proliferation of weapons of mass destruction in the arsenals of various countries has raised alarms regarding global peace and security.

The present situation, coupled with recent advancements in the life sciences, has placed today's scientists in a position similar to that of the atomic physicists of the early 19th century. Research carried out in various area of life sciences, and in biotechnology in particular, can have profound impacts on generations to come. The present era is characterized by revolutionary advances in the life sciences. These advances have benefited the human race immensely in terms of new and novel ways of treating

diseases, making effective diagnoses, bettering human health, developing desired agricultural traits, etc. In addition, living organisms can now be modified by introducing a variety of novel features into them. However, such knowledge also has the potential to be misused (2). Such technologies are now referred to as "dual-use technologies" and the research that has the potential to be misused is known as "dual-use research." The current, 21st century is considered to be the century of biology. The research carried out in this era will have a profound impact on the future of humanity, making current, biological research critical in the whole history of biology in terms of policies and decision-making on dual-use concerns.

Pakistan has flourished and made great strides during this era in the life sciences. According to the projections of statistics, if future research proceeds at the same pace as of today, by 2018 Pakistan will rank 27th among the world's countries in scientific advancement. Within a span of just two years, the number of scholarly publications has increased two-fold. In fact, Pakistan publishes more peer-reviewed research articles per capita than India (4).

During 2015, approximately 10 to 15 PhD degrees are awarded each week in Pakistan. PhD enrollments have increased 40% and the number of M.Phil/MS enrollments increased by 65% (3). Furthermore, the PhD faculty in public sector universities has increased by 50% in two years, during 2012–2014.

Pakistan is an emerging market for biotechnology in as much as discoveries can be used for the betterment of health and social and economic well-being. In 2010, the biotechnology-based revenue in Pakistan was 1.4% of Gross Domestic Product (GDP) which is expected to rise in the future. Research in the life sciences, involving more than 200 departments, has quadrupled during the last decade, i.e., 2000-2010 (4). Pakistan's biotech industry has been a government priority since the country opened its first biotechnology plant in 2010 (5).

This volume focuses on the conceptual framework, ethical dimensions, and dual-use concerns of science and technology. There are growing concerns among Pakistani scientists and, indeed, within the entire Pakistani scientific community about dual-use issues. These concerns focus on overwhelming security issues due to terrorism in Pakistan. This volume discusses various topics in dual-use education, such as dual-use dilemmas, bioethics, bioterrorism, biosafety, biosecurity, etc. Numerous examples are presented that illustrate threats to the human race from dual-use issues. This volume also serves as an organized, comprehensive and concise, source of information tailored to Pakistan's national and educational contexts, for students, scientists and educators. The book includes discussions of biosafety and biosecurity measures, as well as the management of dual-use issues. It also includes information about the efforts of Department of Biotechnology, Quaid-i-Azam University, Islamabad, along with other national and international partners, to promote education about dual-use issues and responsible conduct by scientists.

The basic concepts concerning dual-use education in biotechnology are elaborated below.

1.1 Dual-Use and the Dual-Use Dilemma

Dual-use represents scenarios in which the outcomes of legitimate scientific research can be used for both good as well as malicious purposes. This definition provides the basis for what is now widely known as the "dual-use dilemma" (6). Simply stated, the main purpose of scientific research is to serve humanity from all walks of life, but a dual-use dilemma arises when such beneficial research is misapplied for nefarious purposes. The life sciences and the current advances in biotechnology can be exploited for benevolent and malevolent applications (7) and, therefore, need to be subjected to strict

regulation. The major problems in regulating dual-use issues are first, the difficulty in anticipating the risk factors associated with a scientific research activity, and second, knowing how to mitigate those risk factors without creating hurdles to the ongoing research (7). Numerous cases are discussed in the later section about dual-use in the life sciences.

With the ongoing debate on dual-use issues, it is imperative to answer the following question: Why should Pakistan care about the debate over dual-use? Firstly, it is a well-established fact that Pakistan has been in a war against terrorism for the last several decades and as a result has suffered massive economic and manpower losses. In these circumstances, non-state actors might use novel strategies to inflict damage on the state. They might use engineered biological weapons against both the state's military and its general population, resulting in a holocaust. Dual-use research has the capacity to equip the terrorist with even more virulent biological weapons than those existing at present. Major pillars of Pakistan's economy are agriculture and livestock farming, any nefarious act involving biological weapons could bring about severe disruption of the country's economy. The debate on dual-use issues will result in streamlining of national policies on science and technology, healthcare, agriculture, and industry. Such debate will also foster the creation of proactive biorisk management plans which eventually will benefit the state.

1.2 Bioethics and the Responsible Conduct of Scientists

Ethics are concepts which guide us in distinguishing between good and bad, right and wrong, etc. (8). When ethics are considered in the context of life sciences, they are referred to as bioethics. Researchers must pay close attention to becoming responsible scientists by conducting their activities with complete upstanding of bioethics. Because scientific research influences the society and can have profound impacts on people's lives, it is therefore critical for scientists to gain the support and trust of the public. People may benefit or be harmed as a consequence of their research. Resources can also be wasted and misused (8). The subject of bioethics is a considerable one. However, only a brief overview of the scientists' responsible conduct and ethics in research is presented here. In the section below, we will try to find an answer to the question that what makes a responsible scientist?

Plagiarism is a common problem faced by scientists in which the work of one scientist is copied by another scientist and claimed by the latter as his or her original work. The "CTRL-C" and "CTRL-V" dilemma, i.e., the copy-and-paste protocol of most computer programs, is well-known to Pakistani researchers and students. Even many high-profile officials are accused of plagiarism. Sometimes, "citation amnesia" leads to plagiarism but in truth, this situation simply represents an irresponsible review of the literature. Citing irrelevant contributors and denying authors credit when writing a review of literature needs to be avoided (9). Gift, prestige and ghost authorships credited in published materials also need to be avoided. The same is true regarding publishing in LPU's (Least Publishing Units). There are cases of scientific publications in which not only involve plagiarism but also denial of credit due to a contributor in research inventions and publications. At the global level, a high-profile dispute arose between Robert Gallo and Luc Montagnier on the discovery of the Human Immunodeficiency Virus (HIV) regarding propriety issues (10). An author may not list others' contributions due to having preeminence in the contest for propriety (8). Apart from that, regulatory guidelines also need to be implemented for scientific journals in order to sort out what should be published and what (content) needs to be avoided. It should be mandatory for all scientific journals and periodicals in the field of biology to have an ethical review committee that would fairly evaluate the bioethical and dual-use concerns in scientific discoveries and publications.

The tradition of intermixing religion and science may become problematic. However, present-day scholars of different religions have developed their opinions about the cutting edge technologies. In a country like Pakistan, where religion is of paramount importance, it is imperative that scientists elucidate the religious perspectives relating to a particular research project. Although many people stress that religion and science should be kept separate, in a society where ethical principles are governed by religion, it is not possible to do so.

1.3 Biosecurity

"Biosecurity" or applied biosecurity refers to the principles, technologies and practices that are implemented to secure pathogens, toxins and sensitive technologies from unauthorized access, loss, theft, misuse, diversion or intentional release (11). "Biosecurity" is a term having broad application in environmental security, agricultural security, food security, etc. The term is also used in describing the long-term effects of Genetically Modified Organisms (GMOs), and invasive species (12). The facilities at universities and research centers where work on pathogenic microorganisms and biological toxins is conducted should be completely protected so that no unauthorized person can have access to such facilities. Being complacent and taking (safety in) biosecurity issues for granted can lead to severe economic damage (2). Biosecurity means safeguarding all sensitive material, information, employees, assets, etc. If any of these were to fall into the hands of criminals and anti-state actors, there could be devastating consequences for the safety and security of health and economy of the entire population.

1.4 Biosafety

In the literature, the terms "biosecurity" and "biosafety" are often used interchangeably. However, they have different meanings. Biosafety is defined in the World Health Organization (WHO) Biosafety Manual as "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release" (13). The WHO encourages incorporation of biosafety principles into national policies. Simply stated, the difference between biosafety and biosecurity is that biosafety aims to protect people from germs while biosecurity is meant to protect germs from (the acts of) people (14). With these concerns in mind, Pakistan has already developed the National Biosafety Centre (NBC). Under Section 31 of the Environmental Protection Act, Pakistan established the National Biosafety Committee that operates within the National Biosafety Centre. The Pakistan Biosafety Rules were codified in 2005. There are three levels of administrative bodies regarding the NBC (2).

1.5 Bioterrorism and Biological Weapons

Basically, biological weapons are those which are made up of four integral parts which are payload, munitions delivery system and dispersion system (15). The payload represents the biological, infectious entity or toxin produced by microorganisms, animals or plants. Munitions used to containerize the biological material in a delivery system which can be either a missile or any other carrier such as an aircraft, a ship, etc. Lastly, the dispersion system provides a launch pad for the effective dissemination of the biological material by providing a spray mechanism (16). Such biological agents possess certain characteristics which make them a popular choice of non-state actors. These include low cost and easy production, easily accessible knowledge for production, lowered chances of detection because of invisibility (aerosols), and simple logistic requirements. Therefore, biological infectious entities or toxins are known as the poor man's bomb (17, 18). It is estimated that using a Bioweapon/km^2 would

cost just US$ 1/Km^2 as compared to conventional weapons which cost approximately US$ 2000/km^2 (19). Genetic engineering techniques can be used to create engineered biological weapons that can effectively evade barriers and, thus, bring about more damage. Following the nuclear missile test in 1998, Pakistan was accused of having an offensive, biological weapon program. As a consequence, sanctions were imposed on the country's various biological research centers but these sanctions were lifted because there was no evidence to support them (20). Being a signatory to the Biological Toxin and Weapon Convention (BTWC), Pakistan favors the use of biological entities only for peaceful purposes (2).

1.6 Biodefense

There is no doubt that the hostile, biological weapons programs by hostile states or anti-state actors plus naturally-emerging and reemerging infectious pathogens pose great security challenges for Pakistan. Biodefense basically refers to "procedures that are involved in taking defensive measures against attacks using biological agents" (21). Biodefense is a broad term which includes the counter-measures taken against bioterrorism. Defensive strategies include not only the emergency responses by military and health authorities when there has been an exposure to a biological weapon but also the regulations and policies to curtail and alleviate any chances of bioterrorism.

Category A	Category B	Category C
Conatgious, Easy dissemination, High mortality, Public panic, Social dirsuption	Moderatly easy to disseminate, Modrate mobidity Low mortility	Have the potential to be used as bioweapon by genetic engineering and enhancing the dissemination
Bacillus anthracis *Clostridium botulinum toxin* *Yersinia pestis* *Variola major* *Francisella tularensis* *Ebola* *Marburg*	*Brucella* *Salmonella* *Escherichia coli* *Burkholderia mallei* *Burkholderia pseudomallei* *Chlamydia psittaci* *Ricin toxin*	*Nipah virus* *Hanta virus* *Tickborne encephalitis* *Multidrug-resistant tuberculosis*

Figure 1.1: Biological weapons categories (http://emergency.cdc.gov/agent/agentlist-category.asp).

References

1. Covey, S.R. (2013). *The 8th Habit: From Effectiveness to Greatness*. Simon and Schuster.
2. Selgelid, M.J., & Rappert, B. (Eds.). (2013). *On the Dual-Uses of Science and Ethics: Principles, Practices, and Prospects*. ANU E Press.
3. Shinwari, Z.K., Khalil, A.T., & Nasim, A. (2014). Natural or deliberate outbreak in Pakistan: How to prevent

or detect and trace its origin: Biosecurity, surveillance, forensics. *Archivum Immunologiae et Therapiae Experimentalis*, 62(4), 263-275.

4. The Nation (2013) http://www.nation.com.pk/pakistan-news-newspaper-daily-english-online/islamabad/24-Jun-2013/pakistan-becomes-major-player-in-world-research (Accessed: 5th Jan, 2014)
5. Shinwari, Z.K., Mancini, G.M., & Pinnard, W.J. (2011). Introduction to Biorisk Management and Dual-Use in Life Sciences. Landau Network Centro Volta.
6. Aldridge, S. (2009). Pakistan's first biotech plant. *Nature Biotechnology*, *27*(9), 788-788.
7. Selgelid, M.J. (2009). Governance of dual-use research: an ethical dilemma. *Bulletin of the World Health Organization*, *87*(9), 720-723.
8. Elward, C. (2013). Dual-use research of concern: Practical policy approaches to best avoid misuse in the life sciences. The Spectra, p. 11-20. Available at: www.seas.virginia.edu/pubs/spectra/pdfs/**dualuse**.pdf (Accessed date: 25thApril, 2015).
9. Shamoo, A.E., & Resnik, D.B. (2003). *Responsible Conduct of Research*. Oxford University Press.52
10. LaFollette, M.C. (1992). *Stealing into Print: Fraud, Plagiarism, and Misconduct in Scientific Publishing*. University of California Press.
11. Clevestig, P. (2009). *Handbook of Applied Biosecurity for Life Science Laboratories*. Stockholm: Stockholm International Peace Research Institute.
12. The definition is based on World Health Organization (WHO). *Biorisk Management: Laboratory Biosecurity Guidance* (WHO: Geneva, Sep. 2006), <http://www.who.int/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/>, p. 6–8; Organisation for Economic Co-operation and Development (OECD), Directorate for Science, Technology and Industry, Best Practice Guidelines on Biosecurity for Biological Resource Centres (OECD: Paris, 2007), <http://www.oecd.org/>, p. 8; and International Biorisk Standards Development Initiative Secretariat, 'Laboratory biorisk management standard, CWA biorisk public enquiry', 25 July 2007, <http://www.biorisk.eu/documents/draft_document.PDF>, pp. 7–13. CWA stands for CEN Workshop Agreement; CEN stands for Comité Européen de Normalisation (European Committee for Standardization).
13. World Health Organization, *Laboratory Biosafety Manual* – 3rd edition, World Health Organization, Geneva.
14. WHO, *Laboratory Biosafety Manual* – 3rd edition. Available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/ (Accessed on: 25th April, 2015).
15. Sidell, F.R., Takafuji, E.T., & Franz, D.R. (1997). *Medical Aspects of Chemical and Biological Warfare*. Office of the Surgeon General (Army), Falls Church, VA, USA, p. 415-423.
16. Hawley, R.J., & Eitzen Jr, E.M. (2001). Biological weapons – a primer for microbiologists. 1. *Annual Reviews in Microbiology*, *55*(1), 235-253.
17. Atlas, R.M. (1998). Biological weapons pose challenge for microbiological community. *ASM News*, 64, 383-388. Available at: www.asm.org/ccLibraryFiles/.../July98%20Atlas%20feature.pdf. (Accessed on 1st March, 2015).
18. Nettleman, M.D. (1991). Biological warfare and infection control. *Infection Control*, *12*(6), 368-372. 1
19. Huxsoll, D.L., Patrick, W.C., & Parrott, C.D. (1988). Veterinary services in biological disasters. *Journal of the American Veterinary Medical Association*, 190 (6), 714-722.
20. *Jane's CBRN Assessments,* 20 March 2012, Department of Commerce, Bureau of Export Administration, "India and Pakistan: Lifting of Sanctions, Removal of Indian and Pakistani Entities, and Revision in License Review Policy; Final Rule," Federal Register, Vol. 66, No. 190, 1 October 2001, www.bis.doc.gov; "Proliferation (Pakistan), Biological," , http://articles.janes.com.
21. http://www.nlm.nih.gov/medlineplus/biodefenseandbioterrorism.html (Accessed 7th Jan., 2015).

Chapter 2

Dual-Use Dilemmas in Biotechnology: Examples, Issues and Concerns

Ali Talha Khalil[1], and Sohail Ahmad Jan[2]

Department of Biotechnology, Quaid-i-Azam University, Islamabad
[1]talhakhalil.qau@gmail.com, [2]sjan.parc@gmail.com

Benign research in life sciences has massive potential to be misused, either intentionally or unintentionally. The rapid growth in biotechnology in recent years has offered great benefits globally, but as one of the most rapidly-growing areas of science in the early 21st century, biotechnology also brings security risks that must be recognized and effectively addressed. The so-called ''dual-use dilemma'' arises in the context of research in biological and other sciences as a consequence of the fact that one and the same piece of scientific research sometimes has the potential to be used for harm as well as for good.

If one compares the dual-use risks of biotechnology and those of some other fields of science, one can conclude that the risks associated with biotechnology should be considered with a more cautious eye than the rest – because the biological materials are relatively difficult to handle. Furthermore, radioactivity can be detected from afar; this is not the case with biological materials. Pathogenic viruses and bacteria are present in natural environments. They cannot be detected from a distance and are self-replicating as well. It's easy to create a biological infectious agent because there are few technical hurdles to doing so. In addition, nuclear technology is not advancing at the same rate as biotechnology, a circumstance that creates more chances of novel discoveries in biotechnology which can pose dual-use dilemmas (1). Rather various biotechnologies are growing at an exponential rate and the time taken from a discovery to its application is very short.

Modern biotechnology began in the 1970s, two decades after the discovery by Watson and Crick of the DNA double-helical structure. In 1973, Cohen and Boyer provided the basic methodology to create a recombinant DNA molecule, i.e., combining the genes of different organisms which is referred to as rDNA technology or genetic engineering. Genetic manipulations allowed scientists to produce human insulin, the development of which laid the foundation of the modern biotechnology industry (2). With the explosion of techniques in the modern era such as genome mapping, sequencing, proteomics, synthetic biology, etc., there developed sufficient information to understand biology at the molecular level. It is now possible to produce drugs and chemicals and to express peptides in bacteria. Similarly, with the advent of nanobiotechnology, it is now possible to engineer a molecule that can, for example, facilitate a drug's entry into the blood stream (3). However, such molecules can also be used for germ warfare (3). Synthetic biology can be used to assemble a biological weapon from scratch (4). The following paragraphs discuss some fairly famous examples of biotechnical research with dual-use concerns:

2.1 Resurrection of the Spanish Influenza Virus

In 2005, Jeffery Taubenberger from the US Armed Force Institute of Pathology, along with his fellow

researchers, sequenced full genome of the Spanish influenza virus which years ago caused a deadly pandemic and that took approximately 50 million people's lives worldwide (5). Further, research on the sequence lead to the synthesis of the influenza strain containing the same eight gene elements of the Spanish influenza virus from 1918. Interestingly, the virus which was created as a result of this research was found to be more harmful to chickens than any other flu virus. The rationale behind this research was to develop new treatment strategies such as drugs and vaccines, and to shield the human race against pandemics of influenza in the future (33). There is also a strong possibility that such data could be used by criminals, anti-state agents and bioterrorists for their own nefarious objectives.

2.2 The SPICE Experiment

In 2002, a research study was published in the Proceedings of the US National Academy of Sciences regarding an engineered protein called SPICE (Smallpox Inhibitor of Complement Enzymes) produced by the smallpox virus. This study explained how the SPICE protein is able to defeat and evade the human immune system (6). The findings indicated a strong potential for drug discovery and showed a way to enhance the pathogenecity of *Vaccinia* virus which, resembling the smallpox virus, is used in vaccine production against smallpox (34). However, this research also raises a dual-use concern since it shows the mechanisms employed to evade the human immune system.

2.3 Synthesizing the Polio Virus

Researchers at the State University of New York were able to create the polio virus using the published RNA genome map available on the internet (7). Investigators ordered, purchased, and stitched the corresponding DNA strands together and then added them to a cell juice. The cell juice contained all the cellular ingredients except the live cells. This experiment resulted in the production of synthetic polio virus which paralyzed and killed mice (34). This experiment was published in the journal, Science, in 2002. This research came under the spotlight of dual-use concern because it sent the message that biological weapons can be created without obtaining a natural virus (8). In 2008, the SARS virus was synthesized in the laboratory (19). A dual-use concern is that the same methods can be used to assemble deadly viruses like Ebola.

2.4 Vaccine-resistant Smallpox Virus

In order to develop a strain of mousepox virus that could induce infertility in mice, Australian researchers used genetic engineering techniques to insert the interleukin gene (IL-4) into mousepox virus. To their surprise, the investigators found that they had created a super-strain of mousepox virus which not only killed the mice which were naturally resistant to the mousepox virus but also killed those which had been vaccinated against mousepox virus (9). The publication was criticized because of the sensitive information it contained which could be exploited and misapplied. Such techniques can also be employed for the production of vaccine- resistant smallpox virus, for which the only method of protection is vaccination. This study appeared in the Journal of Virology in 2001 (34).

2.5 Transmission of the Avian Influenza (H5N1)

Another important case with dual-use research concerns involves the experiments on avian influenza transmission among ferrets. Those experiments provide the best model for influenza transmission in humans. It is assumed that the viral strain H5N1 killed about 60% of infected humans but in 2015 it

is also assumed that the strain is not transmissible from person to person. There were experiments conducted by researchers in the United States and Holland in order to find out if H5N1 might in the future be able to evolve into such an entity that could be transmitted from person to person. Genetic engineering of the virus and passaging of the modified virus created a strain which was easily transmissible among ferrets. This research indicated that the person-to-person transmission of H5N1 might be possible. Publishing such a research is debatable. Some researchers argue that such research should be published and made public because although it will not facilitate the production of vaccines and drugs against H5N1, it will provide an opportunity to monitor changes in the H5N1 strain. Other researchers argue to the contrary that the H5N1 human-transmissible strain, if produced and unleashed accidently, or intentionally by bioterrorists, could kill millions of people (33).

2.6 Producing a Hypervirulent TB Strain

Tuberculosis (TB) is a devastating disease that causes 10 million deaths per year worldwide. In an experiment aimed at producing mutants of *Mycobacterium tuberculosis* lacking the ability for nutrient uptake, a hypervirulent, mutant strain of *Mycobacterium* was created. The studies showed that this mutant strain had increased virulence in vitro compared to that virulence found in the in vivo studies (29).

2.7 Engineering Proteins

Proteins, made up of amino acids, play a pivotal role in the structure and function of the body. They regulate biochemical processes occurring inside the body. With the help of protein engineering, tailor-made proteins can be produced either by modification or by creating them from their component elements. These engineered proteins have a number of uses in industry but at the same time, they can be exploited for malevolent purposes (10). Protein engineering technology basically has three techniques, known as “rational design”, “directed evolution” and “artificial proteins”. In the first technique, i.e., rational design, the amino acid sequence of the protein is modified to change its 3D shape and function (11). In directed evolution, the DNA sequence is shuffled to produce thousands of mutant proteins. All of those mutants are then screened through highly sensitive processes to find the mutant having the desired function (12). Some researchers consider these mutant proteins extremely harmful to human cells (1).

The third approach entails the introduction of unnatural amino acids to the natural ones to create artificial proteins (13). Protein engineering techniques have benefited pharmaceutical industry because of the fusion toxins. Various protein toxins like animal toxins (venom from snake, spider etc.), plant toxin (ricin from *Ricinuscommunis*) and bacterial toxins (botulinum and diphtheria toxins) have the ability to incapacitate the cellular machinery at very low doses because of their selective interference (1). Generally these toxins have a catalytic domain which is responsible for the toxic effect and a binding domain that enable its binding to various receptors (14). Researchers have made a fusion toxin by binding the catalytic domain of ricin toxin to interleukin-2 which kills the cancerous cells and leave the normal ones. Such fusion toxins are already in the market against T-cell lymphoma (15).

Besides the advantages of the technology, protein engineering also owes certain dual-use concerns. Protein engineering may be used for enhancing the toxicity of protein toxins like ricin and botulinum which are already used as biowarfare agents (16). Fusion toxins can be modified to enhance the abusive uses. For instance, catalytic domain of Shiga toxin is bounded with the binding domain of anthrax toxin, the resulting product can be used to target a vast range of mammalian cell lines (17).

Another concern regarding the protein engineering is the engineering of prions that may become more harmful and devastating to human beings (18).

2.8 Synthetic Biology

The 20th century was marked by the great advancements in nuclear physics but the 21st century is more poised towards biology perhaps because of the emerging and most ambitious subject known as synthetic biology (20) which is defined as "the synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature" (21). Synthetic biology provides de novo solutions to technical problems which can either be a novel feature of the existing organism (mostly bacteria) or assembling a new organism entirely (31). The visionaries of biology are of the opinion that if all the promises of synthetic biology were fulfilled then biology can turn to rather a transformed mechanistic science likewise the transformation in the field of chemistry by the invention of periodic table (21). An important objective of synthetic biology is to produce standard biological parts with quality controlled procedures and then assemble them in the form of novel biological systems. Since 2003, there are global events and competitions about the systemic engineering and display of biological parts by BioBricks foundations and MIT (22). These international symposiums, expos and competitions help scientists to effectively apply the biological information and technology. The number of biological parts which have become been public by virtue of international Genetic Engineered Machines has increased several folds.

Practically synthetic biology has the potential to bring massive advancements in the life style of the human race but there are some areas that can get great benefit from the applications of synthetic biology such as biopharmaceuticals and biomedicine, sustainable chemical industry, energy and environment, biomaterials and counter measures against bioterrorism (21). Recently, the bioengineering of metabolic pathways of yeast for artemisinin production (23) and producing bioengineered microbes for the production of biofuels (24) are some of the examples that how synthetic biology can be used for improving the life standards. However, synthetic biology has become a controversial area because synthetic biology presents numerous opportunities to be misapplied (35). With the help of this technology, stability and efficiency of the biological weapons can be increased while it can also be used to create new, novel and potent biological weapons.

2.9 Shuffling the DNA

The rationale behind DNA shuffling is to accelerate the process of evolution by manipulating the genome of an organism for enhancing the protein expression or enzymatic activities. DNA shuffling represents a kind of directed evolution which produces such genetic variations which normally do not occur in nature (25). This technology when applied on microorganisms, it has enhanced the diversity of these microorganisms beyond the natural means of evolution which are then used to screened the microorganisms having the desired characters. DNA shuffling is used in the production of more effective enzymes and therapeutic proteins, etc. (25). This technique is also employed in the production of phenylalanine which leads to the production of aspartame (nonnutritive sweetener) (26). DNA shuffling can also be misapplied and it can be used for increasing the capacity of certain characters that bring harm. DNA shuffling can be used for increasing the pathogenesis, toxicity, increasing drug resistance, etc. Applying this technique for biological weapons can produce biological weapons that are even more catastrophic.

2.10 Personal Genomics

Due to rapid advances in the bioinformatics tools, sequencing technology and our ability to recognize genes which are somehow associated with the diseases have lead us to the era of personalized medicines. Tailored drugs can be used according to one's genetic makeup. Genetic information can be used for more effective treatment of a disease. Once the price of human genome sequencing is dropped down to a feasible level, personalized medicines may have a revolutionary impact on the healthcare of human beings (27). Besides the great promises in the field of medicines, personalized medicines possess certain dual-use implications as well; however, they haven't been utilized for any nefarious purposes to date. Theoretically, there is a possibility that in the future such biological and chemical agents can be made that could be effective against a specific cast. Some critics suggested that such information and data can even be used to design a bioweapons against specific ethnic groups (28).

2.11 Bioregulators and Neuroscience

Bioregulators are natural and small biological components that regulate the cellular processes, like hormones or peptides. Basically they are utilized in biotechnology to induce a particular function in organisms. For instance, many plant bioregulators are used to induce flowering and stimulate growth. Bioregulators have also been used to benefit human race (30). Some scientists are of the opinion that some types of bioregulators have the tendency to incapacitate the human immune system while others can make the immune system compromised. Some bioregulators can be used to deliver a toxin to a desired site of the human body. There are dual-use concerns over the bioregulators like intentional change of behaviors and emotions. Visionaries of the dual-use research also argue that bioregulators can be used directly for military purposes such as changing the emotions and feelings of a soldier to cause high pain resistance (30). Cytokines, Chemokines, Eicosanoids (prostanoids and leukotrienes), Neurotransmitters and hormones are bioregulators (32).

2.12 Conclusions

Prevention of the hostile applications of biotechnology is not a matter concerning United States only, but it's a matter of humanity in general. Countries have to think above their security challenges and move together to cope with these issues. Technology governance is an important issue regarding dual-use research in life sciences. Broadly, the governance measures for dual-use research can be categorized into 3 categories, i.e., hard law, soft law and normative. Hard law represents the international treaties such as arms control and export control, etc. which provides legal binding between the signatory states. These also includes the international conventions such Biological Toxin Weapon Convention (BTWC), Chemical Weapon Convention (CWC), etc which prohibit the signatory states to refrain from involvement in the hostile use of technology. Soft law represents the measures that are not legal such as voluntary guidelines by the ISO (International Standard Organization) and self regulatory proposals by the industries and laboratories, etc. Lastly, the normative measures are less formal as compared to the soft law and include professional codes of conduct, education and awareness. Normative issues aim to create a responsible, secure and safe scientific culture. Technology monitoring will play a critical role in risk assessment and risk mitigation of dual-use research. Initial investigation of the dual-use potential of a research should be carried out by the scientist involved in the experiment and later by Biosecurity Task Force (BTF) and Institutional Biosafety committees (IBC's) which can evaluate research for the risks associated with it through its proper guidelines which are subjected to periodic review.

References

1. Tucker, J.B., & Flanagan, M. (2010). *Double-Edged Innovations: Preventing the Misuse of Emerging Biological/Chemical Technologies* (No. ASCO-2010 018). Monterey Institute of International Studies, CA James Martin Center for Nonproliferation Studies.
2. Chyba, C.F., & Greninger, A.L. (2004). Biotechnology and bioterrorism: An unprecedented world. *Survival*, 46(2), 143-162.
3. Trapp, R. (2008). Advances in science and technology and the chemical weapons convention. *Arms Control Today*, 38(2), 18.
4. McLeish, C., & Nightingale, P. (2007). Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy. *Research Policy*, 36(10), 1635-1654.
5. Taubenberger, J.K., Reid, A.H., Lourens, R.M., Wang, R., Jin, G., & Fanning, T.G. (2005). Characterization of the 1918 influenza virus polymerase genes. *Nature*, 437(7060), 889-893.
6. Rosengard, A.M., Liu, Y., Nie, Z., & Jimenez, R. (2002). Variola virus immune evasion design: expression of a highly efficient inhibitor of human complement. *Proceedings of the National Academy of Sciences, 99*(13), 8808-8813.
7. Cello, J., Paul, A.V., & Wimmer, E. (2002). Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template. *Science*, 297(5583), 1016-1018.
8. Pollack, A. (2002). Traces of terror: the science; scientists create a live polio virus. *New York Times*, *12*.
9. Jackson, R.J., Ramsay, A.J., Christensen, C.D., Beaton, S., Hall, D.F., & Ramshaw, I. A. (2001). Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. *Journal of Virology*, *75*(3), 1205-1210.
10. Bartfai, T., Lundin S.J., & Rybeck B. (1993). *Benefits and Threats of Developments in Biotechnology and Genetic Engineering*. Stockholm International Peace Research Institute, SIPRI Yearbook 1993: World Armaments and Disarmament (Oxford: Oxford University Press, 1993), 297.
11. Tucker, J.B., & Hooper, C. (2006). Protein engineering: security implications. *EMBO Reports*, *7*(1S), 14-17.
12. Tucker, J. B. (2012). *Innovation, Dual-Use, and Security: Managing the Risks of Emerging Biological and Chemical Technologies*. MIT Press.
13. Benner, S.A., & Sismour, A.M. (2005). Synthetic biology. *Nature Reviews Genetics*, *6*(7), 533-543.
14. Millard, C.B. (2005). *Medical Defense against Protein Toxin Weapons.* Humana Press, p. 255-283.
15. Foss, F.M. (2001). Interleukin-2 fusion toxin: targeted therapy for coetaneous T cell lymphoma. *Annals of the New York Academy of Sciences*, 941(1), 166-176.
16. Business Insight Report, (2007). *Next Generation Protein Engineering and Drug Design: Strategies to Improve Drug Efficacy and Improve Drug Delivery*. Available at: http://www.globalbusinessinsights.com/content/rbdd0013m.pdf. (Accessed on: 22nd April, 2015).
17. Arora, N., Williamson, L.C., Leppla, S.H., & Halpern, J.L. (1994). Cytotoxic effects of a chimeric protein consisting of tetanus toxin light chain and anthrax toxin lethal factor in non-neuronal cells. *Journal of Biological Chemistry*, 269(42), 26165-26171.
18. Saborio, G.P., Permanne, B., & Soto, C. (2001). Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding. *Nature*, 411(6839), 810-813.
19. Nyssa, S. (2008). Man-made SARS virus spreads fear. Canberra Times, December 24, 2008. Available at: http://www.abovetopsecret.com/forum/thread421736/pg1. (Accessed on: 23rd March, 2015).
20. Fidler, D., & Gostin, L.O. (2008). *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law*. Stanford University Press.
21. Tucker, J.B., & Flanagan, M. (2010). *Double-Edged Innovations: Preventing the Misuse of Emerging Biological/Chemical Technologies* (No. ASCO-2010 018). Monterey Institute of International Studies CA James Martin Center for Nonproliferation Studies.
22. International Genetically Engineered Machines (iGEM) Competition 2009. Available athttp://2009.igem.org/About. (Accessed on: 26th March, 2015).

23. Ro, D.K., Paradise, E.M., Ouellet, M., Fisher, K.J., Newman, K.L., Ndungu, J.M., & Keasling, J.D. (2006). Production of the antimalarial drug precursor artemisinic acid in engineered yeast. *Nature*, 440(7086), 940-943.
24. Atsumi, S., Hanai, T., & Liao, J.C. (2008). Non-fermentative pathways for synthesis of branched-chain higher alcohols as biofuels. *Nature*, 451(7174), 86-89.
25. Epstein, G.L. (2010). DNA shuffling and directed evolution. In: B.B. Tucker, J.B & Flanagan, M. (Eds.), *Double-Edged Innovations: Preventing the Misuse of Emerging Biological/Chemical Technologies*. Defense Threat and Reduction Agency, p. 191-208.
26. Dannert, C.S. & Arnold, F.H.. (1999). Directed evolution of industrial enzymes. *Trends in Biotechnology*, 17 (4), 135-136.
27. Mohan, N. (2010). Personal genomics. In: B.B. Tucker, J.B & Flanagan, M. (Eds.), *Double-Edged Innovations: Preventing the Misuse of Emerging Biological/Chemical Technologies,* Defense Threat and Reduction Agency, p. 223-232.
28. Stein, R. Genomes of Archbishop Tutu, Bushman decoded in developing-world health push. *The Washington Post*, (February 18, 2010). Available at: (http://www.washingtonpost.com/wpdyn/content/article/2010/02/17/AR2010021702466.html). (Accessed on: 14th April, 2015).
29. Connell, N. (2013). The Super TB Experiment: Evolution and Resolution of an Experiment with Dual-Use Concerns. In: B.B. Selgelid, M.J. & Rappert, B. (Eds.), *On the Dual-Uses of Science and Ethics: Principles, Practices, and Prospects*, ANUE Press, p. 87-96.
30. Shinwari, Z.K., Mancini, G.M., Pinnard, W.J. (2011). In Introduction to biorisk management and dual-use in life sciences, Landau Network Centro, p. 69-91.
31. Glass, J. I., Assad-Garcia, N., Alperovich, N., Yooseph, S., Lewis, M. R., Maruf, M., & Venter, J. C. (2006). Essential genes of a minimal bacterium. *Proceedings of the National Academy of Sciences of the United States of America*, 103(2), 425-430.
32. Madsen, J.M. (2005). *Bio warfare and terrorism: toxins and other mid-spectrum agents* (No. USAMRICD-P05-027). Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground Md., p. 273-279.
33. Selgelid, M.J., & Rappert, B. (Eds.). (2013). *On the Dual-Uses of Science and Ethics: Principles, Practices, and Prospects*. ANU E Press.
34. Selgelid, M.J. (2009). Governance of dual-use research: an ethical dilemma. *Bulletin of the World Health Organization*, 87(9), 720-723.
35. IAP. (2014). IAP Statement on Realizing Global Potential in Synthetic Biology; Scientific Opportunities and Good Governance. Available at: http://www.interacademies.net/10878/Scientific_Opportunities_and_Good_Governance.aspx. (Accessed on: 30th June, 2015).

Chapter 3

Responsible Conduct of Science

Irum Iqrar

Department of Biotechnology, Quaid-i-Azam University, Islamabad
irum_rao@hotmail.com

Responsible conduct of science (RCS) is defined as "the practice of scientific exploration with reliability and integrity" (1). It involves the awareness and implementation of established professional and ethical norms in activities performed by the scientific community (1). Ethics must be entrenched in scientific research and life scientists must first seek to do no harm. It is the practice of scientific research and investigation with moral integrity. "Scientists have a special responsibility when it comes to the problems of 'dual-use' and the misuse of science and technology" (Inter Academy Panel).

Science is based on values which include morality, fair-mindedness, sincerity and collegiality. Scientific innovativeness of supreme practicality, efficiency, and vision is helped through these values. As long as these values are privileged, research in the scientific community will prosper in the society (2).

Responsible conduct of science is the part of ethical norms which involve the integrity of science. Several sources of ethical norms and scientific conduct strongly forbid the misuse of science (2). This chapter discusses the principles of responsible conduct of science and the codes of conduct for scientists.

3.1. Principles of Responsible Conduct of Science

Research institutes, universities, public and private research organizations and funding organizations must witness and endorse the principles of responsible conduct of science in scientific and scholarly research. These principles include (3, 4):

- Scholarly and scientific rigor;
- Integrity in obtaining, recording and analysing data;
- Integrity in reporting and publishing results;
- Refraining from fabricating or falsifying data or results;
- Mentoring students to become good scientists; and
- Responsibility of the scientists and researchers regarding integrity of science.

It is the responsibility of institutes and its researchers to ensure the security of all those who are directly or indirectly associated with the research. The plan of research should take into account all aspects of security and safety. It must conform to the proper strategies on the use of material, storage and proper disposal of waste (3, 16).

Research in life sciences is a significant effort that has profited the society by evolving our understanding of living structures. Regardless of a scientist's meticulous approach to research conduct, the knowledge, products, or technologies resulting from some life sciences research may be misused to pose a threat to public health, agriculture, plants, animals, the environment, or material (5).

The content of responsibility is concerned with the fundamental query "What should scientists do"? Life scientists in any stage of research must have a moral responsibility to minimize the risks and harm that could result from malicious use of research results (5, 9). Scientists have the right to express their opinions and make efforts for community change and these actions need not weaken a rigorous commitment to objectivity in research.

3.2. On Being a Scientist: Scientific Practices towards Responsible Conduct of Science

For the integrity of scientific research, moral scientific practices are essential in order to foster confidence within the research community and the larger society. Open, translucent and replicable research permits the discourse obligatory to better the science for development and progress in scientific research. It implies that review committees and publishers must take into account the importance of bringing potential security and safety issues related to research activities during review process (3, 19).

Responsible conduct of science encompasses the following areas; collaborative research, laboratory safety measures, publication practices and responsible authorship**,** peer review and the meticulous avoidance of research misconduct (i.e., plagiarism, fabrication and falsification).

3.2.1. Collaborative Research

Scientists should take part in doing collaborative research in a variety of ways, which includes sharing, lending and borrowing of resources, ideas and equipment. Researchers can get knowledge from someone proficient in a different field or collaborate with colleagues having same background or field of study for new ideas and abilities. There is a need to focus on quality of scientific and interactive communications and interactions within the labs and amongst collaborators. "Collaborations become essential whenever researchers wish to take their research programs in new directions" (6).

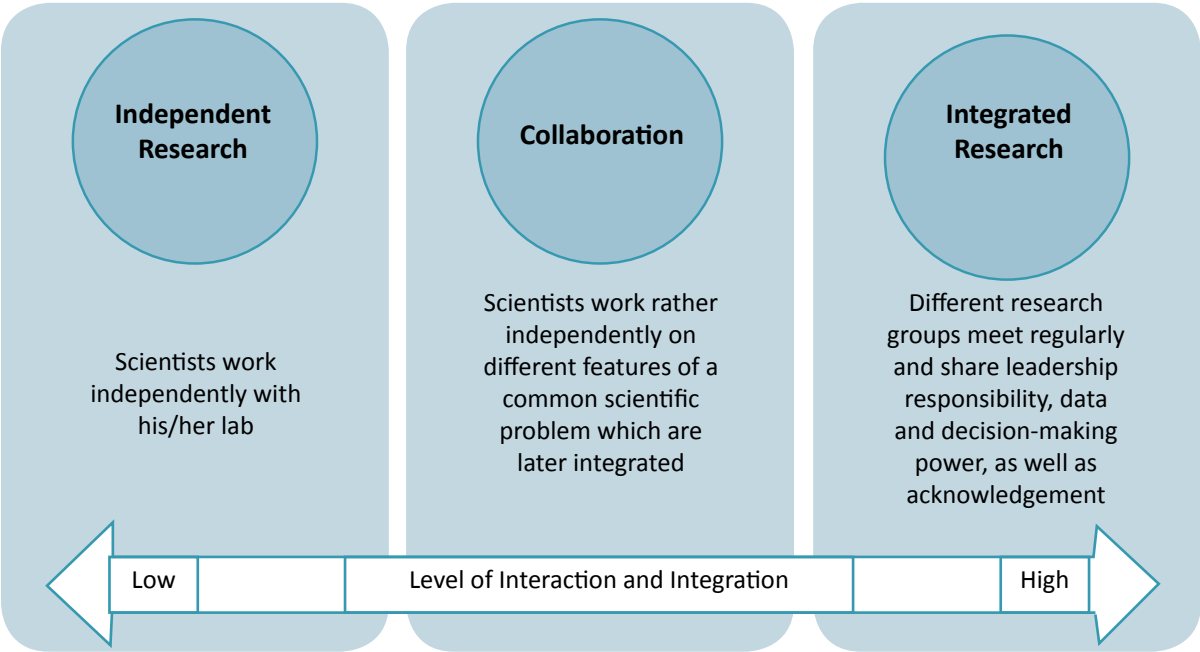


Figure 3.1: A continuum of interaction and integration (6).

Researchers have done a great job by harnessing techniques, approaches and viewpoints from multidisciplinary scientific groups which was not possible within one laboratory working in isolation. Novelties and developments are now emerging as a result of collaborations which increase the level of interaction and integration among research teams as shown in Figure 3.1 (6).

3.2.2. Laboratory Safety Measures

Laboratory safety measures must be implemented that include biosafety and bio-risk analysis built on the hypothesis of human frailty and foible while determining whether a particular protocol should be allowed. Accidental exposure to Ebola in 2014 caused a safety specialist to ask: How can we make research labs safer? By studying these upheavals, and the major and minor errors that could cause breakdowns in labs, we can better understand and prepare for what can go wrong, whether it is caused by human error or intentional malfeasance (7).

Safety issues regarding laboratory protocols should be reviewed at least once a year. These include (3):

- Training of staff before entering the laboratory;
- Proper usage of sensitive equipment;
- Safe handling of materials in laboratories;
- Safe removal of harmful materials, i.e., Ethidium Bromide;
- Safety management and responsibility;
- Safe transference of materials between laboratories;
- Emergency comebacks; and
- Applicable government regulations and guidelines.

3.2.3. Human Participants and Animal Subjects in Research

Research based on human participants and animal subjects implies moral and ethical responsibility in daily life and have explicit implications in the context of research. Scientists who conduct studies with human participants and animal subjects need to keep the interest of research subjects in mind by conforming to relevant codes established by research organizations and institutions (3). Human subjects related sensitive research data may need to be secured.

It's imperative for the scientist to follow ethical guidelines when dealing with human and animal subjects. The official laws and guidelines must certify conduct of responsible science and focus on the safety and security of human and animal research subjects.

In response to widely publicized examples of research misconduct, i.e., experiments based on human participants by the Nazis to study the Tuskegee syphilis of the U.S. Public Health Service, and the mistreatment incidents on laboratory animals forced many countries to adopt such laws (8, 10). One approach to lessen such incidents would be that researchers must give surety to their organizations and to funding sources that their research follows the established principles of responsible conduct.

3.2.4. Publication Practices and Responsible Authorship

The outcomes of research can be published in various ways; mostly published as an article in any prestigious journal. Standard publication practices should be followed by researchers when publishing the results of research and not issue any early public announcement about the research till it has been

gone through by reviewers. In team work the research group leader should be followed by the entire group members so that others know who did the research work and should be acknowledged and get credit for it (3, 8). *Authorship* is generally limited to individuals who make major contributions to the research work that is published. There should be:

- No diplomacy or compromise;
- No fighting or confrontation;
- Coordination and collaboration; and
- Friendly and Cooperative environment.

3.2.5. Peer Review

During peer review, researchers have responsibilities for reviewing the research of others (8, 10). Peer review suggestions improve and evaluate the quality of scientific research papers. Articles designated as peer-reviewed infer that each constituent of the published article has received the editorial consent and approval. This includes the addition or deletion of materials after the initial review process. After submission of the manuscript it may be essential to change or modify it only with the approval of the editor (3, 8).

3.2.6. Scientific Misconduct

Scientific misconduct is the violation of principles and norms of responsible science in many ways – from a lack of care in the application of scientific methods or in recording data, to deliberate fabrication or deception (3). A person who engages himself in such activities not only threatens the reputation of science but also puts his scientific career in jeopardy. Institutions and organizations should have fundamental measures in place for investigating the scientists involved in research misconduct and also should have strategies to protect both informers and the suspect until a determination is made (3, 11).

Scientific misconduct is "**fabrication, falsification or plagiarism** in recommending, executing or revising research or in publishing research outcomes" as given by **USA Office of Research Integrity (ORI)** (3). Scientists have special responsibilities by virtue of doing scientific research, such as:

- Do not fabricate or falsify data;
- Do not plagiarize, and attribute credit properly; and
- Mentor students to become good scientists.

Fabrication: Fabrication implicates assembling of results and recording them as if they are real. A person involved in such activity may have earlier received any academic credentials taken away (3, 8).

For example, University of Konstanz took away Jan Hendrik Schon's doctorate degree because he was found guilty of misconduct (fabrication) related to research done during his service in 2004 (14).

Falsification: Falsification involves manipulating research material including apparatus or procedures or altering or removing results such that the study is not accurately presented in the record of research (3).

Plagiarism: Plagiarism is the seizure of other's material without giving proper acknowledgment or credit (3).

3.2.6.1. Four Levels of Plagiarism

- *Repetition*: Simply copying from an unrecognized source.
- *Patching*: Copying, with joining phrases, from several sources.
- *Plagiphrasing*: Paraphrasing from several sources and joining them, placing in the reference list but without page numbers.
- *Conventional Academic Writing*: Where ideas are created to make a dispute and a new academic package but are they new idea? (13).

Failure to fulfill clear moral, ethical and lawful necessities such as opening of privacy, lack of up-to-date consent, and misuse of research subjects are included in other forms of misconduct. It also includes inappropriate dealing with defilements, such as efforts to hide misdemeanors and punishment of informants. Mentors have the responsibility towards the mentee to correct them if they are involved in any minor wrongdoings which may be damaging for probable incidence (3, 16).

3.2.6.2. Consequences of Scientific Misconduct

The response to scientific misconduct must be proportional to its solemnity and as a rule it should be confirmed that whether the misconduct was done irresponsibly, purposefully or intentionally. The effects of misconduct within the scientific community may lead to reputation damage, personal infidelity and even can be demoralizing (3, 19). It could lead to:

- It could end the career of a researcher by taking away credentials and rewards.
- It may also lead to dismissal of tenured faculty.
- Forfeiture of research grants.
- Blacklisting (e.g., research institutes and reputable universities refuse to give employment; journals refuse to publish any articles; funding sources refuse to give funds for research work, etc).

3.3. Responsible Conduct in Dual-Use Research

Dual-use dilemma arises as a consequence of scientific research which may have the ability to be used for good as well as harm (15).

'With significant dives in scientific and technological progressions, science has presumed both beneficial and disparaging roles worldwide and, therefore, the need for responsible conduct of science and biosafety precautions is momentously felt'(20).

The dual-use potential of life science research is substantial. Although all research may be used in more than one way and might impose some example of harm to someone, not all research has the ability to cause significant harm. In the past era, the dual-use dilemma has gained attention due to an increasing apprehension that life science research can be misused for biological weapon (BW) purposes (14).

There are five essential concerns faced by scientists while doing research in the life sciences: information, awareness, education and responsibility, security and safety, and lapse (oversight) which were addressed in the Inter-Academy Panel (IAP) statement, given in 2012. Life scientists have the responsibility not to contribute to the construction and development of biological weapons (BW), this has become a fundamental part of the dual-use discussion whether deliberately or accidently (17).

3.4. Responsible Use of Science in Pakistan

Responsible and ethical use of science endows advances in the fields of agriculture, environment, medicine and veterinary science. Pakistan recognizes the importance of responsible conduct. Several steps have been taken to evaluate and alleviate risks, while getting the most out of the benefits in all relevant fields. To reinforce the execution of the World Health Organization (WHO) International Health Regulation of 2005, actions are being taken by the Pakistan's National Institute of Health (NIH).

In the fields of agriculture and veterinary sciences, Nuclear Institute for Agriculture and Biology (NIAB), Pakistan Agricultural Research Council (PARC), National Institute of Biotechnology and Genetic Engineering (NIBGE), and National Veterinary Laboratory (NVL) are well-known to endorse harmless and nontoxic usage of biological agents. The National Bioethics Committee under Pakistan Medical Research Council (PMRC) has been recognized to manage medical research to certify that research is accomplished within ethical standards, which is under the Ministry of Health. (2).

Pakistan is taking the responsibility of ensuring conduct of responsible science and organizations have taken a lead role to connect various research organizations for an oversight on the research activities of life sciences (18, 19). Some of the aims of these organizations are:

- To endorse the notion of the conduct of responsible science amongst scientists themselves.
- To be well aware of the concept of plagiarism, fabrication and falsification in research.
- To encourage the concept that scientists should not misuse science to harm humanity.
- To stimulate esteem for the scientific careers in a way suitable for a civilized society.
- To develop a sustainable system that regularly takes account of strategic issues related to the conduct of responsible, safe, secure and ethical science in the framework of a progressive society.
- Biosafety and biosecurity issues and the essential steps needed to be taken at individual, social and governmental level.

Terence Thomas Taylor, President of the International Council for Life Sciences (ICLS) said, 'Scientists should carry out additional responsibilities to overwhelming safety and security apprehensions and by endorsing the culture of responsibility among scientists, laboratory accidents and bio-risks could be reduced' (20). Dr. Anwar Nasim, Chairman, ICLS (Pakistan Chapter), said "Scientists should be role models and play their role in making positive changes in the society" (20).

In view of this, Department of Biotechnology, QAU, in collaboration with LNFV, IAP and PAS planned to conduct training workshops for educating life scientists about "responsibility in conducting research" which will be discussed in Chapter 6.

3.5. Conclusions

Scientists have the most important responsibility for maintenance of values and ethics of responsible conduct in research. They have responsibility towards themselves, their colleagues, mentee and humanity to evade the flagrant wrongdoings of plagiarism, fabrication and falsification and also other practices of negligent conduct counterproductive to research innovativeness. They must observe established laws and principles and pay attention towards the established ethics of their field of research. While planning a research project, researchers must keep in view the probable outcomes of their research, including destructive concerns. They also must be willing to share data of their

outcomes with others, and agree on the morals and ethics to be followed in multidisciplinary alliances.

Funding organizations should provide funds and support to research institutes for the progress of education and training workshops on conduct of responsible science. The funding agencies should evade rules and strategies that might overemphasize quantity over quality in the incentive systems for scholars. Research investigator and research institutes should be provided the necessary level of support to ensure that research can be carried out well and dutifully, without conceding veracity. Research institutes should ensure mechanisms are in place to respond to research misconduct. Funding agencies should ensure the implementation of rules and regulations when supporting international research collaborations.

National academies and scientific bodies should provide strong leadership on subjects involving responsible conduct of science and its integrity, including the setting up of principles based on morals and ethics. These organizations should make effort within their own scientific groups to ensure that effective mechanisms exist with clear terms to deal with scientific misconduct.

References

1. Office of Research Integrity. *Ethical and Responsible Conduct of Research*. Available at: http://research.ucr.edu/ori/rcr.aspx
2. Shinwari, Z.K., Mancini G.M., & Pinard, W.J. (Eds.). (2011). *An Introduction to Biorisk Management and Dual-Use in Life Sciences*. Landau Network Centro Volta.
3. National Academy of Sciences, N.A. (2009). *On Being a Scientist: A Guide to Responsible Conduct in Research*. National Academies Press (US).
4. Council, I. (2012). *Responsible Conduct in the Global Research Enterprise*. Inter Academy Council.
5. Report of the National Science Advisory Board on Biosecurity (2012). *Enhancing Responsible Science: Considerations for the Development and Dissemination of Codes of Conduct for Dual-Use Research*. Available at: http://osp.od.nih.gov/sites/default/files/resources/COMBINED_Codes_PDFs.pdf
6. Bennett, L.M., Gadlin, H., & Levine-Finley, S. (2010). *Collaboration & Team Science: A Field Guide*. NIH Office of the Ombudsman, Center for Cooperative Resolution.
7. Huntley-Fenner, G. (2015, January 2). Ebola lapses show lab safety protocols should factor in human error. *Los Angeles Times*. Available at: http://www.latimes.com/opinion/op-ed/la-oe-huntley-disease-lab-safety-20150102-story.html (Accessed: January 10, 2015)
8. Steneck, N.H. (2007). *ORI: Introduction to the Responsible Conduct of Research*. Government Printing Office, Revised Edition.
9. Nordgren, A. (2013). *Responsible Genetics: The Moral Responsibility of Geneticists for the Consequences of Human Genetics Research (Vol. 70). Springer Science & Business Media.*
10. Steneck, N.H. (2003). *ORI: Introduction to the Responsible Conduct of Research*. Government Printing Office.
11. Office of Research Integrity (ORI) Annual Report (2010). Department of Health and Human Services.
12. Vogel, G. (2011, September 19).Jan Hendrik Schön Loses His Ph.D. *SCIENCEINSIDER*. Available at: http://news.sciencemag.org/education/2011/09/jan-hendrik-sch%C3%B6n-loses-his-ph.d. (Accessed: 10th Dec. ,2014)
13. D'Arcangeli, L. *How to Avoid Plagiarism*. Available at: http://www.lucianadarcangeli.com/site2_eng/howtoavoidplagiarism.htm
14. Kuhlau, F. (2013). *Responsible Conduct in Dual-Use Research: Towards an Ethic of Deliberation in the Life Sciences*. Centre for Research Ethics and Bioethics.
15. Miller, S., & Selgelid, M.J. (2007). Ethical and philosophical consideration of the dual-use dilemma in the biological sciences. *Science and Engineering Ethics*, 13(4), 523-580.
16. Drenth, P.J. (2012). A European Code of Conduct for Research Integrity. Available at: http://www.

scienceeurope.org/uploads/GRC/Research%20Integrity/1_PieterDrenth.pdf
17. IAP. (2012) *Summary of IAP Statements*. Available at: http://interacademies.net/10878/3143.aspx
18. International Councilfor the Life sciences. Responsible Conduct of Science – ICLS Pakistan Chapter. Available at: http://iclscharter.org/our-work/responsible-conduct-of-science/ Accessed: 15th January, 2015)
19. Statement of the 2nd Conference on the Responsible Conduct of Science in Lahore, 31 January - 1 February 2011. Available at: http://iclscharter.wpengine.netdna-cdn.com/files/2012/11/Lahore-Statement-Final-10-Feb-11.pdf
20. Statement of the 3rd Conference on the Responsible Conduct of Science in Karachi, 14-15 November 2011. Available at: http://iclscharter.wpengine.netdna-cdn.com/files/2012/11/Karachi-Statement-15-Nov-11.pdf

Chapter 4

Critical Evaluation of Policies of the Government of Pakistan regarding Dual-Use

Sumia Khan[1], and Anwar Nasim[2]

[1]Department of Biotechnology, Quaid-i-Azam University, Islamabad
[2]Pakistan Academy of Sciences, Islamabad
[1]sumiakhan126@gmail.com, [2]dranwarnasim@gmail.com

In the last few decades, the dilemma of dual-use research in the areas of science and technology has become one of the most debated topics, particularly regarding scientific policy. In this regard, the most debated issues are biological weapons and bioterrorists (1). However, security related to sensitive technologies is one of the biggest challenges for scientists and security experts, alike. Therefore, issues related to policy development are becoming more and more important.

4.1 Policy Dilemmas

In the 17th century, the term "dual-use" was used in a negative sense (2). Since then, the threats posed due to biological weapons have grown, and policy regarding dual-use has become the main apprehension of the general public in the modern era. This apprehension increased after the following publications:

- Overcoming resistance to mousepox (3);
- How the Variola virus (smallpox) can evade the immune system (4); and
- On the synthesis of poliovirus cDNA without a natural template (5).

Publications of this nature can be exploited by terrorists for criminal purposes, which have compelled for consideration of changing the research and publication procedures (6, 7, 8, 9, 10, 11, 12). The posting of letters containing anthrax in the U.S. brought about a new discourse to toughen the biological weapons policy (13). After these events, the relationship between the life sciences and development of biological weapons became a significant policy concern (14).

Recent advancements in the fields of life sciences and biotechnology have enhanced the access to technologies used in biological warfare. As a consequence, a considerable number of policy measures were instigated (15, 16, 17, 18) and the research funding in the area of biosecurity have significantly increased.

The implementation of new policies is complicated due to the diffusion of socially beneficial biotechnologies. Scientific policies have the potential to generate significant social costs and to interrupt the acquiring of, and capitalizing on, dual-use technologies. Given this situation, policy makers face a dilemma: how to address both scientific and security concerns, by designing their policies to significantly suppress and restrain biological weapons development while promoting the technologies for legal, scientific purposes (13).

The main concern in the scientific community about dual-use arises in conjunction with the potential misuse of advancements in biotechnologies. The term, "dual-use", also raises many questions about the role of scientists, publishers, and policymakers. They are equally responsible for addressing the developments in biotechnologies which eventually result in more harm than good. There is a famous discourse about the policy regarding dual-use issues which aims to balance the goal of scientific progress and the goal to protect its society (16).

This delicate issue of balancing raises many questions:

- What would be the right balance between security and scientific development?
- How the right balance between these can be achieved, practically?
- What will be the mechanism to achieve this; self-governance or governmental supervision?

The scientific community is in favour of a voluntary, self-governed mechanism in which new codes of conduct would be adopted in order to educate scientists about their responsibilities related to implications of dual-use research. Moreover, scientists think that the solutions to the problem posed by the dual-use research should not solely be controlled by government. They feel that autonomy is indispensable to progress in science, and interference from the government that violates their academic freedom is counterproductive (1).

4.2 Dual-Use Governance and Bioethics

Discussion about the responsibilities of scientists and the governance of dual-use research has largely been between just scientists and security experts. The absence of the voices of bio-ethicists is very unfortunate because, by nature, the dual-use dilemma is an ethical issue, inasmuch as the dilemma is related to concepts of good verses bad, benevolent versus malevolent, and legitimate versus illegitimate use of science and technology. Moreover, the debate over promoting the benefits of new technologies while preventing harm, and the roles of all responsible authorities fall directly within the realm of ethics. In fact, ethics is a discipline particularly concerned with issues of "right and wrong" and the "duties and responsibilities" of human beings (1).

In order to develop an effectual policy for dual-use technologies, the plausible notion is to attain a balance between scientific progress and security. Therefore, to promote security, the aim of policy makers should be to properly regulate science in order to facilitate scientific progress and effective oversight.

Additional, ethical questions arise about the value of scientific progress, the value of security, and how the balance between these should be maintained in case of conflict. For instance, what should be the value of security? Should it be instrumental or intrinsic?

When discussing security and dual-use governance, it is very important to identify the type of security needed for dual-use governance. There are two different concepts of security with respect to the present discussion about dual-use governance. On the one hand, there is the national security approach, which is State-centered. On the other hand, there is the human-security approach (UNDP, 1994), which is individual-centered. Many of the important international treaties related to dual-use concerns were initially rooted in national security. For example, the NPT (Nuclear Non-Proliferation Treaty), the BWC (Biological Weapon Convention), the CWC (Chemical Weapon Convention) and other conventional treaties were originally focused on the military, i.e., the dual-use technologies

related to national security interests. Consideration of criminal intent, including that of terrorists, in international treaties is driven by national security concerns. However, human security is becoming the main focus of national and international consideration; therefore, shifting attention away from national, and toward people-centered, security issues. Considerations of freedom and fundamental human rights are becoming rapidly emerging subjects of dual-use governance, e.g., dual-use export control legislations on surveillance technologies (20). In order to reduce the negative impact of dual-use governance, it is very important to bring clarity in different notions of dual-use. This will help to achieve an optimal level of security while minimizing the negative effects of dual-use governance on academic freedom and, through export control, on censorship of potent dual-use information in relation to public health and development.

4.3 Legislative and Administrative Efforts of Government of Pakistan Regarding Dual-Use Research

4.3.1 Legislative Efforts of the Government of Pakistan

In order to protect and preserve agriculture, people and the environment, Pakistan is determined to introduce bio-friendly legislation. There are a number of laws related to biosecurity issues of Pakistan. Important legislation relevant to biosecurity issues is briefly discussed below.

4.3.2 Pakistan's Environmental Protection Act (1997)

Pakistan's Environmental Protection Act was passed in 1997 by the Parliament of Pakistan. It is regulated by the EPA (Environmental Protection Agency) which works under the Ministry of Climate Change. All the authority of EPA is vested in the Director General who is directly appointed by the Federal Government of Pakistan. This Act mainly involves protection, conservation and improvement of the environment for the control of pollution and promotion of sustainable development. Moreover, this Act also mentions the hazardous substances present in the environment. Under the Environmental Protection Act (1997), the Environmental Protection Agency is empowered to perform the initial environmental examination and impact assessments of proposed future projects (21).

Establishment of Environmental Protection Council under section 3 of the Environmental Protection Act is a positive initiative to promote coordination and collaboration among governmental administrative bodies. The Environmental Protection Council has the power to approve and implement national environment policies. In addition, the Council can recommend new projects to any government agency in order to improve and protect the environment. The Council has investigatory power and can seize property when the Act is violated.

The EPA can serve as the largest regulatory body to counter accidental or intentional threats related to biosafety and bioterrorism. For instance, the regulatory powers of the EPA are not limited to ensuring national environmental quality standards for air and water. The EPA is also the authorized regulatory body for the production, storage, transfer, transport and disposal of hazardous substances. Therefore, in addition to having elaborate and continuous monitoring systems, the EPA can determine threshold levels of potential bio-contaminants in order to counter bioterrorism and conserve the environment.

4.3.3 The Anti-Terrorism Act (1997)

The Anti-Terrorism Act (1997) mainly deals with the issues of controlling terrorism and sectarian violence through establishing special anti-terrorism courts. The Act empowers the federal government

to deploy the civil and armed forces for the prevention of terrorist acts or planned offences in any area. In particular, the Act is focused on ensuring a speedy trial for terrible offences (22).

However, the Act does not throw any light on the crucial issues relating to bioterrorism. Therefore, amendments and additional legal clauses relating to bioterrorism and its management are very much needed to cope with the new challenges lying ahead.

4.3.4 The Pakistan Export Control Act (2004)

Pakistan's Export Control Act, in place since September 23, 2004, is the main legislation controlling the country's regulation of import and export activity. Essentially, the Act controls the import, export, re-export, and trans-shipment of sensitive goods, materials, equipment, and technologies related to biological and nuclear weapons. It also oversees both the diversion and delivery system of sensitive goods and technologies. According to the Pakistan Export Control Act (2004), any heinous offences lead to the penal provision of up to 14 years of imprisonment. In addition, culprits can be penalized for five million rupees. Legislation in the form of the Pakistan Export Control Act (2004) is a vital step to peacefully coexist in the world (23).

4.3.5 The Pakistan Export Control List (2005, 2011)

The Pakistan Export Control List was originally published during October 2005, and was updated in 2011. Periodically, the List is reviewed by members of the Strategic Export Control Division (SECDIV). Notably, the Pakistan Export Control List includes sensitive goods, materials, equipments and technologies in accordance with internationally accepted standard lists. For instance, the List is in accordance with that of the AG (Australia Group) which mainly deals with the MTCR (Missile Technology Control Regime).

Pakistan's updated List as of 2011 contains 19 biologically derived toxins, 13 plant pathogens, 17 animal pathogens and approximately 51 human pathogens which are subject to strict export control regulations (21).

4.3.6 The Biosafety Rules (2005)

Pakistan's Biosafety Rules were formulated in 2005 under Section 31 of Environmental Protection Act of 1997. These Rules principally regulate production, import and storage of the modified micro-organisms and technological products for research involving genetically modified organisms.

The Rules are applicable to all the laboratories, research institutions, and public and private companies working with genetically modified organisms or their products. These Rules also direct field trials related to genetically modified animals, plants, micro-organisms and cells. Furthermore, the Rules are used to regulate import, export, and sale and purchase of any living modified organism, cell and their products or substances for commercial purposes (24).

4.3.7 The National Biosafety Guidelines (2005)

The National Biosafety Guidelines were formulated by the Environmental Protection Agency in 2005. These Guidelines were established to keep genetically manipulated organisms within safe limits, prevent both their deliberate release and adverse effects on human health and the environment. The main purpose of Biosafety Guidelines was to regulate genetically modified materials, and their

derivatives and by-products resulting from genetic engineering practices.

The Guidelines comprise of two parts: the first part deals with regulating work in the laboratories and in the fields; the second part deals with approval processes for regulations, de-regulation, and movement of materials for commercial purposes. Under these Guidelines, all the regulatory work is classified into the following three categories according to the level of anticipated threat and security:

- Work with minimal risk;
- Work with low risk; and
- Work with considerable level of risk.

In order to ensure effective risk management, it is very important to categorize all the regulatory work into various classes so that control measures can be taken accordingly (25).

4.3.8 The National Counter Terrorism Authority Act (2013)

The National Counter Terrorism Authority Act was enacted on March 26, 2013 by the Government of Pakistan. This act was developed to counter the existing menace of extremism and terrorism to the State. The main objective of the Act was to establish a National Counter Terrorism Authority (NACTA), an independent regulatory body directly answerable to the Prime Minister of Pakistan.

Notably, the Authority deals with the collection of information and intelligence in order to disseminate and coordinate with the relevant stakeholders to make adequate and timely efforts to manage the scheduled or unscheduled acts of terrorism and extremism. The Authority also works to formulate and review the State's comprehensive strategies, develop effective plans of action, appoint committees or experts and suggest amendments to the Federal Government (26). However, the Authority neither explains bioterrorism nor the strategies to counter (the issues of) bioterrorism and extremisms.

4.3.9 The National Internal Security Policy (NISP) (2014)

Pakistan formulated its first ever National Internal Security Policy (NISP) in 2014 under two principles. The first was the principle of mutual inclusiveness and the second was the principle of combined national efforts to speak with all stakeholders in order to isolate terrorists and build capacity in security to neutralize internal security threats to Pakistan. The main objectives of the Policy are:

- Establishment of writ of the State to protect life and fundamental rights of its people;
- Promotion of freedom and democracy;
- Prevention and containment of internal security threats in a just and accountable way; and
- Resolution of all disputes with hostile elements in a peaceful manner according to the law.

The Policy includes all security issues in order to ensure public safety, ranging from the enhancement of law to comprehensive boarder control. The NACTA is the main implementing and coordinating authority of the Policy. In order to counter the acts of terrorism and threats to internal security, the Policy encompasses all aspects of terrorism, extremism, sectarianism and militancy. Notably, the Policy also mentions possible, future chemical and biological threats (27).

4.3.10 Recent Counter Terrorism Legislations (2015)

Pakistan is one of the worst terror-affected countries in the world. As it stands, Pakistan is second after

Iraq in the numbers of terror-related deaths (28). Pakistan is afflicted by terrorism in multiple forms. The brutal and worst ever terrorist attack in the history of the Pakistan took place on 16 December, 2014 at the Army Public School in Peshawar where a total of 145 persons lost their lives, including 132 innocent school children.

The Peshawar massacre precipitated significant legislation: Pakistan's National Assembly and Senate formally approved the 21stConstitutional Amendment Bill 2015 and the Pakistan Army (Amendment) Bill 2015 for the establishment of Military Courts in the country. The 21st Amendment was effected on 8th January, 2015. Basically, this Amendment withdrew the provisions of Article 175 of the Constitution, mainly related to the jurisdiction and establishment of the Courts and to the trial of persons under the Pakistan Army Act (1952, 1953), the Pakistan Navy Act (1961) and the Protection of Pakistan Act (2014). According to the draft statement of the 21st Amendment, the extraordinary situation and circumstances existing in the country necessitated special measures and the speedy trial of offences relating to terrorism.

According to recently added sub-sections to the Pakistan Army Act 1952, the Federal Government has the power to transfer the proceeding of any offenses related to terrorism under the provision of Pakistan Army Act to the Special Courts. Moreover, the Act also empowers the Government to penalize any individual, terrorist group or organization for using the name of a religion or sect in connection with terrorism; raising an army for waging war against Pakistan; conducting any terrorist act against civil society, armed forces and law enforcement agencies of Pakistan; as well as kidnapping and/or causing the death of any person under the Pakistan Army Act 1952 (29).

Provisions of these amendments are valid for a period of two years (i.e., 2015–2017). With the approval of these two bills, there is no independent forum for terrorism suspects to appeal against the decision of the Military Courts. Terrorism suspects could not proclaim their rights after being declared as a terrorist by the Military Courts (30).

4.4 Administrative Efforts by Government of Pakistan

4.4.1 National Point of Contact (Global Conventions and Treaties)

In addition to national legislation, Pakistan is also a signatory to as well as an active member of several international biosafety and biosecurity conventions and treaties. A number of national initiatives related to biosecurity and biosafety are explained here under in brief.

4.4.2 The Biological and Toxin Weapon Convention

Pakistan is well aware of the international concerns about bioterrorism and possible use of biological weapons. Accordingly, it has taken a number of legislative as well as administrative steps to prevent and mitigate the risk of bioterrorism. Hence, the Government of Pakistan has been a signatory to this first multilateral disarmament treaty since 1972, namely the Biological and Toxin Weapons Convention (BTWC), and actively takes part in periodic conferences of the BTWC (21). The BTWC is a main pillar of international security architecture. Under Article IV of the BTWC, Pakistan is obligated to take adequate preventative measures to restrict the acquisition, development and stockpiling of any type of weapons of mass destruction, in as much as terrorist groups are active in Pakistan (31) and there are always concerns about possession and use of biological weapons by these groups. Therefore, Article I of the BTWC requires that its member states prohibit the attainment by all state and non-state

members of biological and toxic weapons within states' territories or jurisdiction. Furthermore, the broad definition of Article IV of the BTWC directs various states to maintain control of the diversion and proliferation of sensitive technologies (32). Pakistan believes that such types of multilateral negotiating conventions and treaties are very important in order to promote the agenda of global peace and security (33). Therefore, Pakistan encourages non-signatory states to sign the BTWC and become an ally in order to promote the transfer of biological entities only for beneficial and peaceful purposes (34).

Being a signatory as well as a responsible state, it is obligatory for Pakistan to remain in compliance with various articles of the BTWC.

4.4.3 Draft Legislation for Implementation of the BTWC

The Working Group established by and in concert with the existing governing structure of Pakistan's Ministry of Foreign Affairs, drafted the legislation for implementation of the BTWC. This legislation comprehensively prohibits manufacturing, planning, development, stockpiling, transport, trade, sale, acquisition and possession of biological agents and toxins, as well as their means of delivery. However, the draft BTWC legislation is under review by the Ministry of Law. The Ministry is investigating the draft BTWC legislation in accordance with the national laws before its implementation as a law of the State. The draft BTWC legislation also suggests an Implementation Authority and an Oversight Committee to enhance the existing regulatory system. In addition, this legislation recommends stringent penalties for violating provisions of the legislation (33).

This type of legislation is a positive step towards effective biosafety and biosecurity governance. However, periodic modifications in the light of new economic and geographic challenges are important as well. Therefore, the legislative authorities should be proactive to ensure peace in the world.

4.4.4 The United Nations Security Council

Pakistan is a non-permanent member of the United Nations (UN) Security Council, joining the Council on September 30, 1947. Since then, Pakistan has been elected several times as a member of the Council. In April 2004, the UN Security Council approved Resolution 1540 (UNSCR 1540) describing the Council's essential obligations to UN member states. In particular, the UNSCR 1540 requires all member states to develop appropriate and effective controls against the proliferation of weapons of mass destruction (WMD), including any nuclear, chemical, and biological weapons. UNSCR 1540 narrows the gaps between non-proliferation treaties and conventions. It also helps to prevent non-state organizations from obtaining such dangerous weapons (35).

Pakistan is working actively with the international community to contribute to the global discourse on disarmament and non-proliferation. Notably, Pakistan presented four resolutions on these subjects annually to the United Nations General Assembly. The aim of these resolutions is to reinforce the global norms on conventional arms control, confidence building measures in the regional context, regional disarmament, and negative security assurances to non-nuclear weapon states (36).

4.4.5 The World Trade Organization (WTO) and the Sanitary and Phytosanitary (SPS) Agreement

Pakistan has been a member of World Trade Organization (WTO) since 1995. The World Trade Organization (WTO) is a multilateral organization which deals with the rules of trade between nations.

The main objective of the WTO is to promote smooth, viable, free and fair trade among nations. Therefore, it acts as a forum for trade negotiations, settlement of trade disputes and technical assistance to developing countries to resolve their policy issues (37).

Different articles of the WTO related to biosecurity are confirmed in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement is mainly concerned with human and animal health, along with phytosanitary issues. The SPS Agreement prohibits the import of plants, animals and their derived products if the aim is the introduction of animal or plant pests (38). Pakistan, as a responsible member of the WTO, is committed to the obligations of the SPS Agreement which restricts the country from transporting any containment that can be used intentionally for heinous purposes against plants and animals (39).

4.4.6 The Convention of Biological Diversity (CBD) and Cartagena Protocol on Biosafety

Pakistan has been a member of the Convention on Biological Diversity (CBD) since 1992. The CBD is an international binding treaty whose main objectives are biodiversity conservation, sustainable use of biodiversity, and an equitable sharing of benefits. It covers biodiversity at all levels. Through the Cartagena Protocol on Biosafety, the CBD also covers the field of biotechnology. While recognizing the potential, adverse effect of biotechnology, the Protocol emphasizes the safe handling and transport of Living Modified Organisms (LMOs) (40). In addition, a national biosafety framework is obligatory, in as much as Pakistan is a member state under the provision of Convention of Biological Diversity (CBD) and Cartagena Protocol on Biosafety.

4.4.7 Establishment of the National Core Group of Life Sciences (NCGLS)

In January of 2002, the Higher Education Commission (HEC) of Pakistan established the National Core Group in Life Sciences (NCGLS). The main objectives of the NCGLS were:

- Enhancement of both teaching and research standards in the area of life sciences;
- Identification of the factors directly related to the economy and interests of the country;
- Designing key projects; and
- Development of human resources in the life sciences.

The NCGLS concerns itself with seven main disciplines, namely, bioinformatics, biochemistry, botany, genetics, microbiology, molecular biology and zoology. Realizing the significance and potential of life sciences, the NCGLS established a Working Group comprising of experts and leading life scientists of the country. The main role of the Group was raising awareness and capacity-building in academic institutions.

This Working Group was also engaged in the preparation of standards and biosafety and biosecurity syllabi for students at different educational levels. The NCGLS has launched four resource centers at various universities. A number of national and international conferences, seminars, and training workshops have also been organized in order to raise awareness among scientists and society (41).

4.4.8 The Pakistan Biological Safety Association (PBSA)

The Pakistan Biological Safety Association (PBSA) was established under the auspices of the National Core Group in Life Sciences (NCGLS). The PBSA was officially established on July 21, 2008. It is a non-profit professional organization committed to the comprehensive knowledge of biosafety and

biosecurity issues of Pakistan. The key objectives of the PBSA are:

- To establish a core group of people trained in biological safety;
- To utilize expertise to address the national, biosafety issues; and
- To develop a comprehensive framework in order to promote best practices, standards, and codes of conduct in the life sciences.

A central aim of the PBSA is to advocate for national and international collaboration concerning biological risks (24).

4.4.9 The Strategic Export Control Division (SECDIV)

The Strategic Export Control Division (SECDIV) was constituted in 2007 under the Ministry of Foreign Affairs. SECDIV is responsible to regulate the export of nuclear, biological and missile related technologies and products. The SECDIV also formulates rules and regulations in order to implement the Export Control Act, 2004 (42).

4.4.10 Establishment of an Inter-Agency Working Group (Task Force)

An Inter-Agency Working Group has been established within the Ministry of Foreign Affairs to raise awareness regarding biosafety, biosecurity and non-proliferation of sensitive biological technologies. The Inter-Agency Working Group includes policy representatives and life scientists from the public and private sectors in order to provide a comprehensive input to the Ministry of Foreign Affairs (33). The main aim of an Inter-Agency Working Group is to develop a code of ethics and biosafety laws.

4.4.11 The National Biosafety Center (NBC)

Pakistan established the National Biosafety Center (NBC) under Section 31 of the Environmental Protection Act 1997 for the supervision of biological research and all of its related activities. The overall objectives of National Biosafety Center are to safeguard against the adverse effects of genetically modified organisms (GMOs) and to provide a requisite structure to implement the Biosafety Rules and Guidelines, 2005. Mainly, the NBC contains three administrative bodies: the National Biosafety Committee constitutes the first level; the Technical Advisory Committee constitutes the second level; and the Institutional Biosafety Committee (IBC) constitutes the third level (38, 43).

The National Biosafety Committee is basically involved in the risk assessment, labeling, approval, import export, trade and sale of any living modified organisms. The Committee is empowered to oversee the genetic manipulation work in any laboratory or institution in the country. It also assists the Institutional Biosafety Committee along with other regulatory bodies in establishing codes and guidelines to oversee genetic manipulation research. It also serves as a bridge between foreign biosafety committees and relevant national authorities to address biosafety concerns as well as to observe the international codes of conduct.

The Technical Advisory Committee assesses all the research proposals submitted to the NBC, advising the NBC to either approve or disapprove any project, based on biosafety risks. It reviews all the safety measures and research methodologies adopted for genetic engineering and recombinant DNA technology work. Moreover, it also monitors the environmental release of GMOs during experimental trials and industrial productions with respect to potential biosafety risks and accidents.

The Institutional Biosafety Committee works in close collaboration with the NBC and the Technical Advisory Committee to organize trainings and to ensure that experimental work is conducted in accordance with all biosafety rules and guidelines. It maintains a record of researchers and approved research proposals related to genetic manipulation work. It ensures the health of laboratory and researchers by implementing institutional, emergency and response plans. The IBC has the regulatory power to oversee the ongoing genetic manipulation work within the institute (25).

Looking at the structure of the National Biosafety Centre, one can conclude that it is a comprehensive regulating body which ensures biosafety and biosecurity measures relating to GMOs at each level, from the laboratory to industrial production and beyond.

4.4.12 The National Bioethics Committee (NBC)

The National Bioethics Committee was established by the Ministry of Health, and was officially announced by the Government of Pakistan in the Gazette of Pakistan on 28 January, 2004. The Committee is under the chairmanship of the Director of General Health of Pakistan. This Committee acts as an advisory body to deal with various aspects of bioethics in all sectors of healthcare in Pakistan. The main purpose of the National Bioethics Committee (NBC) is to enhance and facilitate the ethical health research, health education and delivery of ethical health services. The Committee protects all ethical rights of subjects under medical assistance, participants in the research projects, teachers, students and publications in the medical field. It has two sub-committees which work to ensure the protection of ethical rights and equitable distribution of resources:

- The Healthcare Ethics Committee (HCEC) which addresses ethical issues related to medical practices and education; and
- The Research Ethics Committee (REC) which addresses the ethical issues related to research.

The National Bioethics Committee critically monitors and regulates subcommittees which implement the bioethical principles in the health sector of Pakistan (44).

4.4.13 The COMSTECH International Committee on Bioethics (CICB)

Realizing the potential in the crucial innovations of biotechnology, COMSTECH (OIC Standing Committee on Science and Technology) formulated the "COMSTECH International Committee on Bioethics (CICB)" in January 2003. The CICB consists of eminent Muslim scientists from all over the world and is dedicated to addressing various ethical concerns related to medical science, patenting and intellectual property rights (45).

4.4.14 The National Commission on Biotechnology

The National Commission on Biotechnology (NCB) was established by MoST (Ministry of Science and Technology) in 2003. This Commission was formulated to both promote biotechnology and coordinate related activities in Pakistan. It acted as an advisory body to the Ministry of Science and Technology for monitoring the national and international enhancements in biotechnology and for recommending appropriate measures the Ministry might take. It also served as a bridge among universities, research institutes and industry toward a collective effort for commercialization of biotechnology products.

The NCB was fulfilling its financial obligations by the PSDP (Public Sector Development Projects)

project which finished in 2009. Afterwards, the position of Commission could not be restored despite of several requests to Ministry of Science and Technology. In as much as the need to coordinate ongoing biotechnology research and development still exists, it is recommended that the MoST give permanent status to the NCB (46).

4.5 Concerns

Several questions arise when discussing the dual-use research:

- How practical is to develop weapons containing bio-agents?
- Are terrorists and sub-state groups really in a position to produce them?
- Are we prepared for any bioterrorism incident in the future?
- Would controls on the conduct of research and the spread of technology make us safer or place us in greater danger?

There are no simple scientific or political measures which can ensure us that dual-use technologies won't hurt us. But to start figuring this problem out, a vital first step for the scientists will be to overcome their reluctance to discuss dual-use research and biological weapons. Accordingly, awareness of the problem is of paramount importance in the search for solutions.

On one hand the emphasis is on "out of the box solutions", i.e., conducting more research in order to stay ahead of the threats, on the other hand there are worries about shifting funds for inappropriate priorities, boundaries of internationally permissible defense work, and dangers of accidental or intentional release of pathogens (47). With respect to the latter, there are many individuals and facilities working with pathogenic agents due to a significant increase in bio-defense funding. Previously, anthrax attacks in 2001 were planned by an American who worked at the US Army Medical Research Institute of Infectious Diseases (USAMRIID) (48). This incident raised questions about the proliferation of dangerous knowledge, skills and materials due to multibillion dollar biodefense funding. Accordingly, intense discussions are taking place in the US and elsewhere on what sort of screening and oversight of individuals should be done and who should control it. Furthermore, the views of governments and commentators differ greatly on the underlying questions of what the quantity and type of permissible defense work should be.

In order to evaluate the risks and benefits of research instances at the individual level, a number of organizations, funders and publishers have introduced control processes. These control processes are used to determine the need for modification, or withdrawal of proposed research (49). However, misunderstanding of the relationship between science and security needs clarification. In order to avoid conflation, Atlas and Dand (50) have distinguished and explained three dual-use aspects of the life sciences:

- How civilian facilities can be used to develop biological weapons?
- How agents and equipment intended for peaceful purposes can be used in the production of bioweapons?
- How knowledge generated through science can aid those seeking to produce weapons?

It has been suggested that each issue has its own conundrum. If so, a specific type of response would be required in each case. Especially, mandatory international transparency and assessments, in the case of civilian facilities, while in the case of agents and equipment, an oversight and balanced export controls, and overall a culture of responsibility in relation to knowledge.

In addition, more knowledge is not always considered good, at least not completely. The idea of

making researchers more aware of the Dual-Use potential of science and technology, followed by awareness of the general public, is regularly advocated. Much debate exists about just how loudly security concerns should be made known to the population at large (51).

Biosecurity raises serious bioethical concerns. However, bioethicists are paying very little attention to these concerns. Such debate of social responsibility is important, especially in relation to scientific culture (52). Previously, science has been considered both apolitical and neutral; consequently, the ideas of scientific knowledge being inherently good and pursuit of knowledge in science being impartial have been common among scientists (53). In the discussion of social responsibility with respect to nuclear weapons, a commonly advanced idea is that knowledge, science and technology are neither good nor bad; it is the uses of science and technology that are good or bad. Scientists, themselves, have neither the obligation and expertise nor power to prevent illegitimate applications of their work (54). The responsibility to prevent the malevolent uses of knowledge falls on policymakers (1). In other words, scientists engaged in legitimate research are not directly responsible for harmful effects resulting from their ethically neutral pursuits and products. However, private values are often substituted for professional ethical standards. Non-scientists usually refer to their private values instead of to professional ethical standards, and this causes confusion (55).

4.6 Recommendations

The life sciences technologies have immense potential to be misused. Therefore, timely initiatives are required for management of this dual-use dilemma. In this section, certain recommendations are presented that can be useful to mitigate risk.

4.6.1 Capacity Building and Technology Transfer

Capacity building in human resource and infrastructure can be a way forward to cope with the recent challenges of bioterrorism. In this vein, the National Biosecurity Center is very much needed in Pakistan in order to cope with the demanding issues of biological security. Coordination of all the related Ministries and Departments of Health, Agriculture, Livestock and Environment is required. The integral part should consist of national scientists, politicians, technocrats, and threat and security analysts. The role of the National Biosecurity Center should be of an advisory, regulatory, and risk and security assessment body. A geographical information system and an electronic disease reporting system needs to be established that can track down the locality of new pathogenic strains (21). There is also a need to strengthen the national capacity in public health infrastructure, particularly in surveillance and response technologies, to increase vigilance for the deliberate release of biological agents (56).

Moreover, collaboration among national and international scientific and research communities is very important in order to curtail and prevent potential hazards related to advancements in the life sciences. Such collaboration makes technology transfer significantly important. Therefore, developed countries should collaborate and exchange technologies with under-developing countries to address the issues related to dual-use research and bioterrorism. Scientists and students should be directed to vet their research though national and international programmes initiated to resolve any dual-use issue leading to biological weapons.

4.6.2 Effective Legislative Reforms and Oversight of Dual-Use Research

There is an urgent need for biosecurity and bioterrorism legislation to support new technologies

within a legal framework. New legislation related to bio-preparedness, such as a Biodefense Act and a Bioterrorism Act should be developed. Moreover, the existing, comprehensive, public health, food safety, and security policies should be regulated. Scientific communities should play an advisory role to strengthen existing legislation and drive adequate future reforms in national security policy. Periodic review of existing policies is of significant importance in order to ensure the comprehensiveness and effectiveness of biodefense policies.

Oversight and monitoring are needed for:

- Acts of bioterrorism and biological weapon proliferation;
- Human resources;
- Selected lists of globally agreed-upon pathogens; and
- Dual-Use research and technologies.

Another effective strategy to prevent nefarious incidences of bioterrorism would be to monitor the sister sciences, physics and chemistry, both of which could be employed to weaponize even common biological agents (57).

Despite all the excellent existing legislation, there is nevertheless a great need to forcefully implement new biosecurity laws, which is a big challenge for an under-developed country such as Pakistan.

4.6.3 Awareness/ Training and Promotion of a Culture of Responsibility

To implement the best practices for attaining the ultimate degree of biosafety and biosecurity, Pakistan needs to establish a culture of continual awareness and training. Awareness programmes related to preparedness and responsiveness to threats (posed by an outbreak or accidental or deliberate release of dangerous pathogens) should be promoted within the country. Such programmes should include continuous bio-risk management training courses for public health workers to prevent the misuse of scientific advancements (56).

Correcting deficiencies in both the awareness level and education of life scientists is a massive task: it needs involvement of all the stakeholders, including government bodies, funders of life sciences education, responsible administrations of the standards in higher education, civil society, teachers and trainers (58). Training programmes should be initiated to this end. A series of strategic training courses should be instituted for policymakers, laboratory managers by experts in reducing biorisk and implementing biosafety and biosecurity regulations and practices. Adequate attention should also be paid to development of curriculum on biorisk management.

To facilitate biosafety and biosecurity training in developing countries, the biosecurity professionals should be selected from each country for training as trainers, and once trained, they should establish a national biosafety and biosecurity training programme in their own country (56).

The responsibility of the life scientists in relation to deliberate or unintentional biological weapons development and production, has become the central part in dual-use debate (59, 60). Therefore, scientists should be well aware of the potential misuse of their useful knowledge and should evaluate their work in broad, social contexts when considering the potential consequences. Professional responsibility in relation to social obligations is immensely important and requires a new code of ethics to promote a culture of responsibility in relation to scientific knowledge. Dissemination of experiments of concern and dangerous discoveries should be prevented through censorship at both

individual and government levels. Civil society, along with scientists and security experts, should take steps, mutually, against the misuse of scientific knowledge.

4.7 Conclusion and Future Directions

It is extremely important to categorize different stages where precautionary and regulatory measures can operate in order to prevent the malicious use of dual-use technologies. Firstly, we can prevent the malevolent use of dual-use technologies by stopping the most controversial experiments from taking place to begin with. Secondly, dissemination of dangerous discoveries should be avoided, either by promoting a culture of responsibility or through various censorship strategies. A third way can be through limiting the access to dual-use technologies by introducing a mandatory approval system such as the licensing and registration of sensitive technologies, materials and equipment. Last but not the least, strengthening national and international bodies by adding verification measures will help to prevent the use of legitimate technologies for the development of offensive, biological-weapons programmes.

References

1. Selgelid, M.J. (2010). Ethics engagement of the dual-use dilemma: progress and potential. In: *Rappert, B. (Ed.), Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, p. 23-34. The Australian National University, E Press.
2. Bacon, F. (1609). Daedalus, or the Mechanik. In: *Of the Wisdom of the Ancients*. Deer, Brighton.
3. Jackson, B.A. (2001). Technology acquisition by terrorist groups: threat assessment informed by lessons from private sector technology adoption. *Studies in Conflict and Terrorism*, 24(3), 183-213.
4. Rosengard, A.M., Liu, Y., Nie, Z., & Jimenez, R. (2002). Variola virus immune evasion design: expression of a highly efficient inhibitor of human complement. *Proceedings of the National Academy of Sciences*, 99(13), 8808-8813.
5. Cello, J., Paul, A.V., & Wimmer, E. (2002). Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template. *Science*, 297(5583), 1016-1018.
6. Wallerstein, M.B. (2002). Science in an age of terrorism. *Science*, 297(5590), 2169-2169.
7. Cozzarelli, N.R. (2003). PNAS policy on publication of sensitive material in the life sciences. *Proceedings of the National Academy of Sciences*, 100(4), 1463-1463.
8. Malakoff, D. (2003). Researchers urged to self-censor sensitive data. *Science*, 299(5605), 321-321.
9. Purver, R.G. (2002). *Chemical and Biological Terrorism: the Threat According to the Open Literature*. Canadian Security Intelligence Service.
10. Danchin, A. (2002). Not every truth is good. *EMBO Reports*, 3(2), 102-104.
11. Finkel, E. (2001). Engineered mouse virus spurs bioweapon fears. *Science*, 291(5504), 585-585.
12. Kahn, L.H. (2004). Biodefense research: can secrecy and safety coexist? *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 2(2), 81-85.
13. McLeish, C., & Nightingale, P. (2007). Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy. *Research Policy*, 36(10), 1635-1654.
14. Martin, S.B. (2002). The role of biological weapons in international politics: The real military revolution. *Journal of Strategic Studies*, 25(1), 63-98.
15. Atlas, R.M. (2002). National security and the biological research community. *Science*, 298(5594), 753-754.
16. National Research Council of the National Academies of Sciences. Committee on Research, Standards and Practices to Prevent the Destructive Application of Biotechnology. (2004). *Biotechnology Research in an Age of Terrorism: Confronting the Dual-Use Dilemma*. US National Academy of Sciences, Washington, DC.
17. Gaudioso, J., & Salerno, R.M. (2004). Biosecurity and research: minimizing adverse impacts. *Science*, 304(5671), 687-687.

18. Lentzos, F. (2006). Rationality, risk and response: a research agenda for biosecurity. *BioSocieties*, 1(04), 453-464.
19. Anand, S., & Sen, A. (1994). *Human Development Index: Methodology and Measurement* (No. HDOCPA-1994-02). Human Development Report Office (HDRO), United Nations Development Programme (UNDP).
20. Rath, J., Ischi, M., & Perkins, D. (2014). Evolution of different dual-use concepts in international and national law and its implications on research ethics and governance. *Science and Engineering Ethics*, 20(3), 769-790.
21. Shinwari, Z.K., Khalil, A.T., & Nasim, A. (2014). Natural or deliberate outbreak in Pakistan: How to prevent or detect and trace its origin: Biosecurity, surveillance, forensics. *Archivum Immunologiae et Therapiae Experimentalis*, 62(4), 263-275.
22. *The Anti-Terrorism Act (1997)*. Available at http://www.ppra.org.pk/doc/anti-t-act.pdf. Accessed on: 2nd January, 2015.
23. *Export Control Act (2004)*. Available at http://www.mofa.gov.pk/secdiv/documents/Doc-1%20Export%20Control%20Act-2004.pdf. Accessed on: 3rd January, 2015.
24. *Pakistan Biosafety Rules, S.R.O. (I) 336(I)/2005*. Available at http://www.pakbiosafety.com/BiosftyrulesPAK.pdf. Accessed on: 4th January, 2015.
25. *National Biosafety Guidelines, S.R.O. 336(I)/200*5. Available at http://dbtbiosafety.nic.in/act/BiosftyGlines2005_Pakistan.pdf. Accessed on: 5th January, 2015.
26. *The National Counter Terrorism Authority Act, No. F. 9(12)/2013*. Available at http://www.na.gov.pk/uploads/documents/1364795170_139.pdf. Accessed on: 6th January, 2015.
27. Safi, S. (2014). *National Internal Security Policy an A*nalysis. PILDAT (Pakistan Institute of Legislatie Development and Transparency), Pakistan.
28. Institute for Economics and Peace. (2014). *Global Terrorism Index 2014 Measuring and Understanding the Impact of Terrorism, 2014*. Available at: http://shqiptarja.com/pdf/new/Global%20Terrorism%20Index%20Report%202014.pdf.
29. Asad, U. (January 6, 2015). Parliament passes 21st Constitutional Amendment, Army Act Amendment. *Daily Parliament Files*. Available at: (http://parliamentfiles.com/news/parliament-passes-21st-constitutional-amendment-army-act-amendment/). Accessed on: 7th January, 2015.
30. Mubarak, A.A. (January 5, 2015). Two Bills Tabled in National Assembly for Special Courts' Formation. *The Daily Mail International*. Available at: (http://dailymailnews.com/2015/01/05/two-bills-tabled-in-na-for-special-courts-formation/). Accessed on: 8th January, 2015.
31. Negroponte, J. (January 12, 2007). Al-Qaeda 'rebuilding' in Pakistan. *BBC World*. Available at: http://news.bbc.co.uk/1/hi/world/south_asia/6254375.stm. Accessed on: 13th January, 2015.
32. Revill, J. (2007). *Pakistan Biological Weapons and the BTWC*. Pakistan Security Research Unit (PSSRU). Available at: https://www.dur.ac.uk/resources/psru/briefings/archive/Brief1finalised1updated.pdf.
33. Akram, Z. *Statement by Ambassoder Zamir Akram, Perment Representative of Pakistan to the United Nations at the Seventh Review Conference of BTWC*. Geneva, December 6, 2011. Available at: www.opbw.org.
34. Basit, A. *Statement by Abdul Basit, Acting Permanent Representative, at the Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacterial (Biological) and Toxin Weapons and on Their Destruction*. Permanent Mission of Pakistan to the United Nations. Geneva, November 19, 2001. Available at: www.opbw.org.
35. United Nations. (2004). Available at: http://www.un.org/en/sc/1540/.
36. Sharif, M.N. *Statement by His Excellency Mr. Muhammad Nawaz Sharif, Prime Minister of the Islamic Republic of Pakistan during the General Debate of the Sixty-Ninth Session of the UN General Assembly*." New York, September 26, 2014. Available at http://pakun.org/statements/Plenary_of_General_Assembly/2014/09262014-01.php.
37. World Trade Organization. (2015). *Understanding The WTO: What We Do*. Available at: http://www.wto.org/english/thewto_e/whatis_e/what_we_do_e.htm. Accessed on: 12th January, 2015.
38. Roberts, A., Hina, N., Michael, W., and Yusuf, Z. (2013). An analysis of the development and regulation of agricultural biotechnology in Pakistan. *Proceedings of the Workshop on Biosafety Research in Pakistan Grants Program Workshop*, December 13, 2013. COMSATS, Islamabad, Pakistan.
39. Khalil, A.T., & Shinwari, Z K. (2014). Threats of agricultural bioterrorism to an agro dependent economy;

what should be done? *Journal of Bioterrorism and Biodefense*, 5(1), 1–8.

40. The Cartagena Protocol on Biosafety (2000). Available at: https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.Accessed on: 25th April, 2015.
41. Ikram, A. (2011). A case study I: Biosafety and biosecurity in Pakistan. In: *Millett, P. (Ed.), Improving Implementation of the Biological Weapons Convention (The 2007–2010 Intersessional Process),* p. 93-97. United Nations Institute for Disarmament Research (UNIDIR), Geneva, Switzerland. http://www.isn.ethz.ch/Digital-Library/Publications/Detail/?ots591=0c54e3b3-1e9c-be1e-2c24-a6a8c7060233&lng=en&id=134371
42. Khan, M.K. (2008). Nuclear technology proliferation: challenges and international response. *Islamabad Policy Research Institute*, 8(1), 17–38. Available at: http://www.ipripak.org/wp-content/uploads/2014/01/art6khus12.pdf
43. National Biosafety Center (NBC) Directorate (2006). Available at http://www.environment.gov.pk/
44. National Bioethics Committee (2004). Available at http://nbcpakistan.org.pk/
45. Nasim, A. (2005). Biotechnology: Global scenario and international collaboration. In: *H. A. Khan, M. M. Qurashi, T. Hussain, & I. Hayee, (Eds.), Proceedings of South-South and South-North Collaboration Present Scenario and Future Prospects*, p. 39-43. COMSATS (Commission on Science and Technology for Sustainable Development in the South). Available at: http://www.comsats.org/Publications/Books_SnT_Series/05.%20South-South%20and%20South-North%20Collaboration%20(Feb.%202005).pdf
46. Malik, K.A. (2014). *Biotechnology in Pakistan: Status and Pro*spects. Pakistan Academy of Sciences, Islamabad, Pakistan, 60 pp.
47. Enserink, M., & Kaiser, J. (2005). Has biodefense gone overboard? *Science*, 307(5714), 1396.
48. Bhattacharjee, Y. (2009). The danger within. *Science*, 323(5919), 1282-1283.
49. Rappert, B. (2008). The benefits, risks, and threats of biotechnology. *Science and Public Policy*, 35(1), 37-43.
50. Atlas, R.M., & Dando, M. (2006). The dual-use dilemma for the life sciences: perspectives, conundrums, and global solutions. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 4(3), 276-286.
51. Rappert, B. (2007). Biotechnology, security and the search for limits: an inquiry into research and methods. p. 1-198, Palgrave Macmillan. Available at: http://www.palgraveconnect.com/pc/doifinder/10.1057/9780230223158.
52. Jones, N.L. (2007). A code of ethics for the life sciences. *Science and Engineering Ethics*, 13(1), 25-43.
53. Kitcher, P. (2001). *Science, Truth, and Democracy*. Oxford University Press.
54. Bridgman, P.W. (1947). Scientists and social responsibility. *The Scientific Monthly*, 65(2), 148-154.
55. Sture, J. (2010). Educating scientists about biosecurity: Lessons from medicine and business. In: *Rappert, B. (Ed.), Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, p. 35-53. The Australian National University, E Press.
56. Mohammadi, A. (2011). Reducing biological risks by building capacity in health security. In: *P. Millet (Ed.), In Improving Implementation of the Biological Weapons Convention*, p. 191-198. United Nations Institute for Disarmament Research (UNIDIR), Geneva.
57. Chauhan, S.S. (2008). Bioterrorism and biosecurity practical solutions, biotechnology for the sustainability of human society. *13th International Biotechnology Symposium and Exhibition,*12-17 October, 2008, World Expo Center, Dalian, China**.**
58. Dando, M. (2009). Dual-use education for life scientists?. In: *Disarmament Forum,* No. 2, p. 41-44.
59. *Biological and Toxin Weapons Convention (BTW*C). Report of the Meeting of Experts. BWC/MSP/2005/MX/3. Geneva, August 5, 2005. Available at http://www.opbw.org/new_process/mx2005/bwc_msp.2005_mx_3_E.pdf. Accessed on: 27th April, 2015.
60. *Biological and Toxin Weapons Convention*. Report of the Meeting of Experts. BWC/MSP/2008/MX/3. Geneva, September 8, 2008. Available at http://www.opbw.org/new_process/mx2008/BWC_MSP_2008_MX_3_E.pdf. Accessed on: 27th April, 2015.

Chapter 5

Survey on General Awareness about Bio-Security and Dual-Use related Concepts among Educators of Graduate Life Sciences in Pakistan

Faouzia Tanveer[1], and Zabta Khan Shinwari[2]

Department of Biotechnology, Quaid-i-Azam University, Islamabad
[1]fouzia.mirza@live.com, [2]shinwari2008@gmail.com

5.1. Introduction

Dual-Use potential of life sciences research demands that considerable efforts must be directed toward risk assessment and education of the scientists. It is the responsibility of scientists, research institutes and policy makers to promote science which is intended for welfare of humanity but at the same time avoid any harm posed by certain scientific advances (1). Raising awareness about dual-use issues among scientific community is a principal element of educational oversight in order to make scientists recognize their duties and responsibilities.

The Pakistan Academy of Sciences and Department of Biotechnology, Quaid-i-Azam University, Islamabad, have been actively promoting dual-use education in life sciences, especially Biotechnology. They have initiated numerous activities to raise knowledge among life scientists about bioethics, bio-security and responsible science conduct. In this respect, a survey was conducted in Pakistan in collaboration with Inter-Academy Panel (IAP) and Landau Network Fondazione Volta (LNFV), Italy, to assess existence of knowledge about dual-use research issues in faculty of life sciences disciplines in Pakistani universities.

Previously, the results of the survey "Awareness and Opinions on Biosecurity and Dual-Use among Pakistani Life Sciences Students" revealed that overall awareness level about dual-use related concepts was low among a sample of students surveyed from Pakistani universities. Students expressed the need to have experts in the relevant field as well as design courses on the relevant subject to provide proper training and education (2). It was thus recognized that endeavors of promoting dual-use education must incorporate all the stakeholders, i.e., research students as well as educators. Considering the context of education and training for all, assessment of awareness and opinions of the faculty was important in order to identify existing problems related to dual-use education and find solutions to address these problems. The current survey provides a baseline data in order to better understand the attitudes and knowledge of educators/faculty of institutes offering higher education in Pakistan about dual-use dilemma in life sciences and to assess the apparent need for increased awareness and training.

5.2. Survey Methodology

The survey was conducted from August 2013 to October 2014 by Quaid-i-Azam University (QAU) from educators of life science disciplines in various universities across Pakistan (mainly in Punjab and Khyber

Pakhtunkhawa (KP)). It included both quantitative and qualitative data. A total of 651 questionnaires were collected out of which 619 were valid. The aim of the survey was to assess knowledge and awareness level in the faculty/professors of the educational institutes offering life sciences subjects in Pakistan. Moreover, it also aimed to document the opinions and attitudes of educators towards dual-use issues in Pakistan.

5.2.1 Questionnaire

In order to fulfill objectives of the survey, the questionnaire data were collected over two years consecutively. In the first year, 386 and in second year 233 valid questionnaire data were analyzed. The questionnaire was designed on the basis of previous research and surveys with the help of LNFV. However, it was adapted according to the need of Pakistani scientific research. It was mainly composed of close ended questions; however, a few open end questions were also included. Some of the questionnaires were partially filled. The survey results may not be generalized to the overall Pakistani universities/research institutions as a whole due to certain sampling limitations. However, the data may provide a valuable insight into the views of Pakistani scientists (educators) on dual-use issues.

The questionnaire comprised of the following queries:

Questions 1 & 2

The basic concept of terms such as bioethics, bio-security, bio-safety, codes of conduct, bio-weapons and other dual-use related concepts among educators and information about existence of bioethics, bio-security, bio-safety in the curriculum of their respective universities.

Questions 3–5

Awareness about national and international rules and regulations, codes of conduct prohibiting the non-peaceful use of life sciences research and the participation of educators in any seminars, workshops related to dual-use education.

Questions 6 & 7

Opinions and attitudes of educators towards potential misuse of scientific research; need for increased oversight at the national level for safe conduct of science; availability of study material on dual-use and sound policies regulating research and publication with dual-use potential. A question was also posed to know how important these issues are considered by the life scientists/educators, at what level they expect the relevant topics to be taught to the students and what are the difficulties they envisage for inserting these topics in educational curricula.

Open ended questions throughout the questionnaire were useful to gain additional comments and suggestions from the faculty members.

5.2.2 Description of the Sample

The sample was opportunistic as questionnaires were distributed based on willingness of the teachers/professors from different universities. The questionnaires were collected from 29 different universities/research institutions mainly from Punjab and KP province of Pakistan (Figure 5.1). Majority

of the respondents taught MS/MPhil/PhD students in life sciences subjects such as microbiology, biochemistry, molecular biology, biotechnology, agricultural sciences (e.g., plant breeding and genetics), botany, zoology and Pharm D and some taught environmental sciences, bioinformatics, chemistry and physics in their respective universities. The range of courses that were taught during these degrees include recombinant DNA, environmental biotechnology, industrial biotechnology, food biotechnology, principles of gene manipulation, genetics, cell biology, cell culture techniques, immunology, virology, pathology, agronomy, cancer research, pharmacology, pharmaceutical chemistry, agricultural chemistry, proteomics, entomology, plant tissue culture, plant physiology, plant taxonomy and ecology and to a lesser extent research methodology, biosafety and bioethics. Moreover, the number of students taught in each course ranged between 20 to150 per year (Table 5.1) indicating a large pool of young researchers involved in scientific research that needs proper training prior to entering research laboratories.

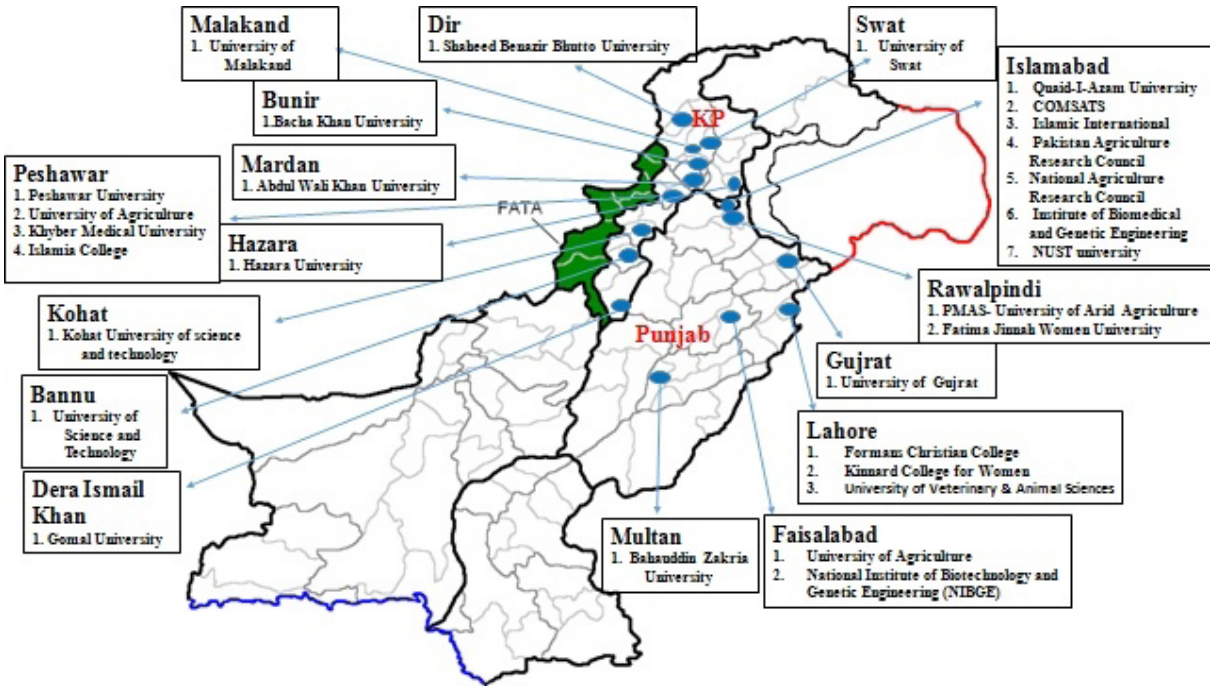


Figure 5.1: Location of Pakistani universities/institutes offering life sciences education/research which participated in the survey.

Table 5.1 Number of students taught in each course per year as reported in the sample survey.

Group	Frequency	Percentage
0-50	253	40.87
51-101	206	33.27
102-152	160	25.84

5.3 Survey Results

Using the above stated survey methodology, we were able to investigate knowledge and awareness of the educators about dual-use concerns in research and the results are presented here.

5.3.1 Knowledge of Basic Dual-Use Concepts (Q 1 & 2)

The first part of the survey assessed the knowledge of educators of graduate life sciences in institutions of higher learning in Pakistan about dual-use related terms. The first question asked "Have you ever heard about the followings?" A large number of respondents seemed well-aware of the terms Bioethics, Biosafety, Biosecurity and Bioweapons for which more than 80% responses were received. The terms Bioterrorism and Codes of Conduct scored 75.05% and 68.47%, slightly less than the other terms mentioned above. However, only 53.18% of the faculty members showed familiarity with the term 'Dual-Use Research'. This is probably because terms like bioethics, biosafety, bioweapons have been in use since long whereas dual-use is a relatively new concept.

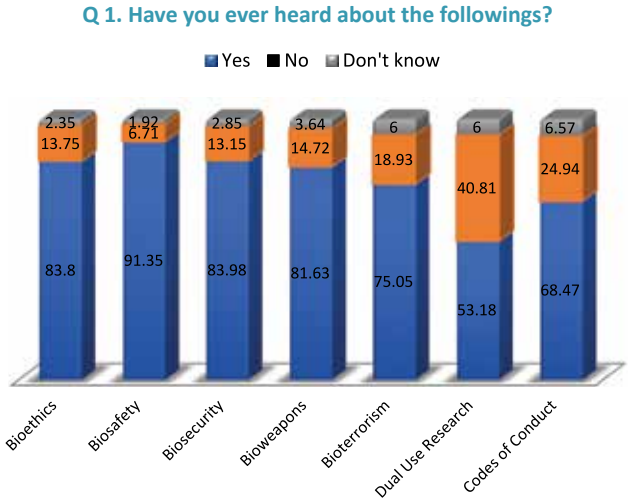
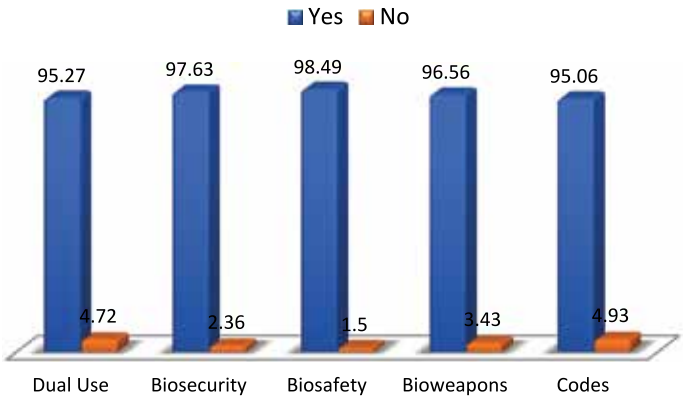


Table 5.2: Proposed definitions of the given terms (Q 2).

Term	Definition
Dual-Use	The term "dual-use" is used to describe technologies that could have both benign and malign usage, specifically in the form of biological weapons. There are at least three different dimensions of dual-use: (1) ostensibly civilian facilities that are in fact intended for military or terrorist bioweapons development and production; (2) equipment and agents that could be misappropriated and misused for biological weapons development and production; and (3) the generation and dissemination of scientific knowledge that could be misapplied for biological weapons development and production.
Biosecurity	In this context, Biosecurity refers to "mechanisms to establish and maintain the security and oversight of pathogenic microorganisms, toxins and relevant resources". In practice biosecurity systems are normally comprised of the following components "Physical protection, personnel reliability, adequate scientific and commercial program oversight, pathogen accountability, transportation security, information security".
Biosafety	In this context, Biosafety refers to "The containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release". There are three key elements to biosafety: "laboratory practice and technique, safety equipment, and facility design and construction".
Bioweapons	Biological Weapons, as defined by the Biological and Toxin Weapons Convention, are: (1) Microbial or other biological agents or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."
Codes	Codes refer to the ethical or practical guidance documents promulgated amongst the community to advice or guide individuals on an issue or issues. Examples include the Hippocratic Oath.

In the second question, certain definitions were given of the terms such as dual-use, biosecurity, biosafety, bioweapons and codes of conduct and the educators were asked whether they agreed or not on the proposed definitions as given in Table 5.2.

Q 2. Please consider the proposed defintions. Would you agree on them?

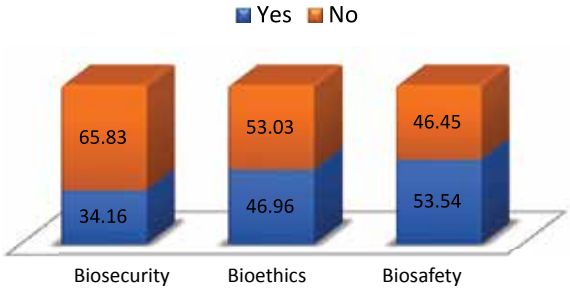


According to the questionnaire data analyzed, above 90% of the educators agreed upon the definitions of all the given terms. Among those who replied "No" to the question, a few of the respondents said they were unaware of these terms and probably could not make an opinion. Thus, they might have preferred to say no to the given definitions. A single aggressive opposite opinion came on the definitions of dual-use and bioweapons. The respondent said that dual-use conflicts with the sanctity of scientific institutions and bioweapons are a threat to peace and prosperity of the nation. This may be rather considered an opinion and not definitions of the respective terms. One respondent who challenged the definition of biosafety said it did not cover all the aspects, however, he provided no further details. Others left the space blank and did not give any reason for saying "No" to the proposed definition they had not agreed with.

5.3.2 Existing Educational Offerings (Q 3–5)

Despite the fact that need for increased education on dual-use related issues has been recognized among the practicing scientists, yet the level of awareness about these issues as well as their scope of incorporation into the existing curriculum is still unknown. Thus, second part of the questionnaire was intended to evaluate the existing educational offerings in research institutions about dual-use concepts. Furthermore, the respondents were enquired about their information regarding national, international regulations and codes of conduct that apply to life scientists.

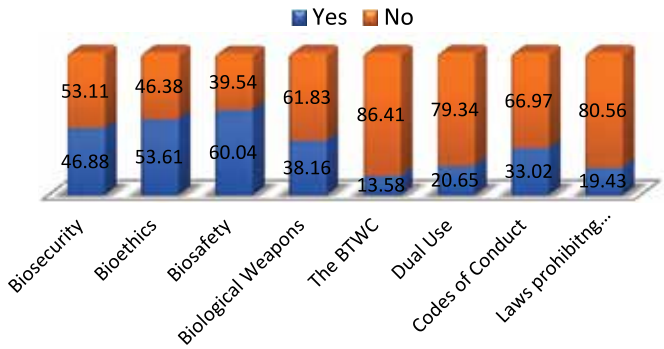
Q 3. During the graduate curriculum you teach, are there any specific modules focused primarily on the following topics?



More than half of the total questionnaire responses given by faculty members informed that topics such as bioethics and biosecurity were not included in the curriculum taught at their universities. The term biosafety scored a little below 50% in this regard (Q 3). Thus there is a need that these topics

may be offered either as separate courses or at least incorporated into the existing curriculum of life sciences disciplines in universities.

Q 4. In the course(s) you teach, or in other courses taught during the graduate curriculum, are there any references made to the following topics ?



Around 45–60% of the respondents agreed that references to the following terms such as biosecurity, bioethics, biosafety were made in the graduate curriculum taught at their universities. For other terms, like biological weapons, BTWC, dual-use, codes of conduct and laws prohibiting biological weapons, quite lower percentages, i.e., 38, 13, 20, 33 and 19%, respectively, were received. The term BTWC secured the lowest percentage among all (i.e., 13%) which shows that it was referenced least in the graduate curriculum of universities included in the survey. Overall, it can be inferred that information regarding laws and regulations was not sufficiently provided and educators as well as institutions and all the stakeholders must take this fact into account. Those who answered "Yes" were further asked to give the name of courses and the nature of the content in which references were made. A greater number of respondents mentioned biosafety, biosecurity, bioethics related courses being offered at their respective universities. Other courses such as nanotechnology, microbial biotechnology, DNA recombinant technology, virology, principles and practices of biotechnology, principles of gene manipulation, medical microbiology, viral vectors and synthetic biology were also mentioned in which references to some or all of the given terms were made.

In response to the question posed to find out whether dual-use related terms appear in any of the course readings, only 46.10% gave positive answers. A few of the educators indicated certain topics that may have been a part of their course readings such as elements of biotechnology, microbiology, viral vectors, laboratory manuals, National Biosafety Guidelines, etc. A few of them mentioned certain books, such as "*Biosecurity in the Global Age*" by David Fidler, "*Handbook of Plant Biosecurity*", "*Bioterrorism*" by APH Publishing Corporation, India, "*Laboratory Biosecurity Handbook*" and "*Environmental Biotechnology*" by Lawrence K. Wang *et al.,* which probably was consulted for the purpose of extracting material for the course work taught to the students. However, a number of respondents left this space blank. A large number of respondents, i.e., 71%, indicated that there was no Institutional Bioethics or Biosafety Committee in their universities. This calls for greater measures to set up an organizational structure in terms of bioethics/biosafety committees at the institutional level in Pakistan. This is particularly important so that life sciences research may be regulated by such committees individually in each institution.

When asked if they had knowledge about organizations concerning the dual-use issues, the majority (79%) were unaware of any local or international organization/ research groups which work on analyzing and regulating dual-use research and biosecurity. A few of those who answered in the

affirmative, mentioned several international/national working groups such as *Center for Environmental Risk Assessment* (*CERA*), *International Council for the Life Sciences* (*ICLS*), *International Service for the Acquisition of Agri-biotech Applications (ISAAA), Organization for Economic Co-operation and Development (OECD*) , *Pakistan Biological Safety Association (PBSA), Environmental Protection Agency (EPA), World Health Organization (WHO)*, *Quaid-i-Azam University and Pakistan Academy of Sciences*. Also, a large majority of educators did not know any international or national regulation prohibiting the non-peaceful use of life sciences research (77% and 84%, respectively). Some of those who gave positive answers frequently mentioned international regulations such as *Cartagena Protocol, Biological Weapons Convention (BWC), Biological and Toxin Weapons Convention (BTWC), WHO Guidelines, OECD Guidelines and National Regulations, such as Pakistan Biosafety Rules (2005), Pakistan Biosafety Guidelines (2005) and Quarantine Laws* in the space provided.

A question posed to find out the level of information about existing codes of conduct in the dual-use related issues among educators revealed that 78.26% were not aware of such codes. Some of the examples mentioned by those who gave affirmative answers included Laboratory Biosafety Protocols, Good Lab Practices (GLP) and Proper Waste Disposal in Lab. Overall, awareness level among educators was low regarding policies and regulations about dual-use related concepts. It seemed that majority of the universities were not offering any separate courses on bioethics, biosafety, biosecurity and dual-use research topics as 69.68% of the educators indicated in their answers and a large number of faculty members (82.84%) had not attended any international workshop or seminar on dual-use issues. Workshops/seminars such as “Introduction to Biosafety” at Heidelberg University (2007), “National Seminar on Biosafety” by American Society of Microbiology (ASM) and “Awareness on dual-use Research” were mentioned by a few respondents who claimed to have attended such events related to dual-use issues. Such a low response to educational offerings related to biosecurity, biosafety and associated concepts highlights deficiencies in the relevant framework of educational and research institutions in the country. It also pointed out lack of nationwide implementation of these issues to address dual-use risks and existence of the need for improvements in risk assessment and policies regarding these topics. There is also a dire need to increase awareness in the scientific community, especially educators, through workshops, seminars, conferences, etc. about dual-use potential of life sciences research.

Educators were questioned whether dual-use related topics were ever discussed among their colleagues and it was found that 70.90% of them never talked about these issues. Bioethics and biosafety were the most debated topics and bioweapons and codes of conduct were slightly less debated during the discussions with colleagues as mentioned by a few of the respondents who gave positive replies. Moreover, a majority of the faculty members (75.40%) denied that they ever conducted or taught research that had dual-use potential, did not believe (63.54% of them) that their field of study involved any such techniques with potential to be misused and 79.61% rejected the possibility of their laboratory set up being used for preparation of some biological weapon. Such denial reflects the consciousness and sensitivity of scientists about these issues. Only 32.30% of educators said to have delivered a lecture dealing with topics such as dual-use research, biosecurity, bioterrorism, etc. owing to lack of availability of experts on the subject. Among all, 65.83% pointed out that there is a lack of educational materials and resources on these issues for educators, emphasizing the need to focus on science-risk based curriculum development or improvement of the existing courses/modules in life sciences/biotechnology. However, surprisingly, 63.04% of the respondents were not willing to change their courses in order to accommodate dual-use related topics. They might be having difficulty finding easy and relevant material to incorporate into the courses they teach.

Only 30% of the universities/research institutions were offering separate courses on dual-use issues. Majority of the courses were designed on bioethics and biosafety as a greater number of positive responses came for these topics. Very few addressed biosecurity and dual-use education. The nature of the contents ranged from biological risk assessment, biosafety levels, biohazard materials, lab biosafety procedures and techniques, Good Lab Practices to mechanisms of implementation of biosafety guidelines, laws related to bioethics in different countries, bioethics and Islam, rules and regulations regarding cross border movements, construction of biosafety committee, etc.

Table 5.3. Please consider the followings (Q 5).

	QUESTIONS	Yes	No
1.	Do the above mentioned topics (biosecurity, dual-use, bioterrorism, biosafety etc.) appear in any of the course readings (bibliography, textbooks…)	46.10%	53.89%
2.	Do you have any Bioethics or Biosafety committee in your Institution?	28.59%	71.00%
3.	Do you know any local or international organization/ Research group that work on analyzing and regulating dual-use research and biosecurity?	20.87%	79.12%
4.	Are you aware of any INTERNATIONAL regulation prohibiting the non-peaceful use of life science research or regulating their oversight (including international treaties, and standards)?	22.37%	77.62%
5.	Are you aware of any NATIONAL regulation prohibiting the non-peaceful use of life science research (including civil and penal legislation, export controls, …)	15.08%	84.91%
6.	Do you know any examples of “codes” of responsible conduct which apply to life scientists and biotechnologists and related professionals?	21.73%	78.26%
7.	Have you attended any international workshop or seminar on biosecurity, bioterrorism, biosafety and dual-use issues?	17.15%	82.84%
8.	Do you think that you conducted, managed or taught research that had dual-use potential?	24.59%	75.40%
9.	Do you think that your field of study involves techniques that have the potential to be misused as defined above?	36.45%	63.54%
10.	Ever you think that your laboratory set up can be used for preparation of material for terrorist activities?	20.37%	79.62%
11.	Have some of your colleagues ever talked to you about these topics?	29.09%	70.90%
12.	Do you have any plans to change your course or module to accommodate such topics?	36.95%	63.04%
13.	Have you ever delivered a lecture dealing with topics such as dual-use research, biosecurity, bioterrorism etc.?	32.30%	67.69%
14.	Do you think there is a lack of educational materials and resources on these issues available for professors?	65.83%	34.16%
15.	Is your University/College offering a separate course covering topics like bioethics, biosafety, biosecurity and dual-use research?	30.31%	69.68%

5.3.3 Opinions and Attitudes of Educators (Q 6 & 7)

The last part of the questionnaire was designed so as to judge the opinions of educators about potential misuse of scientific research rules, regulations and policies about dual-use risks and importance of these issues for the students to be aware of.

Only 28.09% of the respondents felt that laboratory setups at educational institutes can be used to prepare materials for harmful purposes probably because it is rarely expected of scientists to indulge in such activities. However, the possibility of misuse cannot be denied as several cases have been observed in the past where scientists were found involved in dangerous scientific activities. The educators (42.74%) opinionated that it is highly likely that certain undesirable elements can gain access to scientific laboratories and misuse them. The response was not very high as it may not be very easy in reality given the fact that biological materials require special handling and only a scientist may be able to deal with them. Slightly more than half of the respondents agreed that oversight mechanisms and regulations should be increased at the national level to avoid potential harm. Only 30% agreed that scientists have low level of awareness regarding dual-use related national regulations. It implies that probably the implementation of these regulations and not awareness is a greater concern. A number of educators (around 50%) agreed that study materials on dual-use, biosafety and biosecurity should be increased in the course work and policies and regulations must be developed by research funders and government regarding funding of dual-use research. Moreover, 71.56% were of the view that journals must calculate the dual-use risks of scientific data before publishing and 43.96% agreed that misuse of biological knowledge is more destructive as there is no barrier to control it.

Table 5.4. Please tick the appropriate option according to the extent to which you agree or disagree (Q 6).

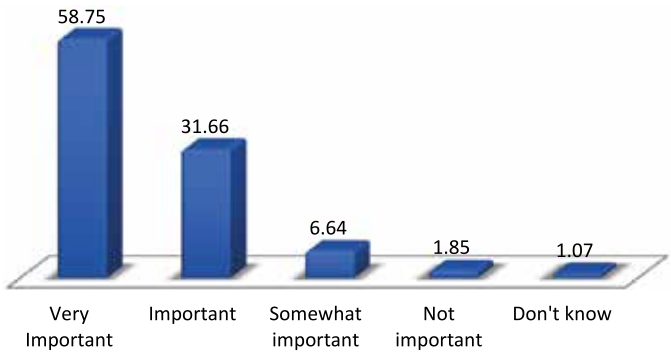
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. Laboratory setups at educational and research institutes can be used for preparation of materials for non-peaceful purposes.	26.08%	26.09%	16.36%	28.09%	4.86%
2. Undesired elements can gain access to scientific techniques, anywhere in the world, to be misused for hostile activities.	17.72%	15.86%	17.29%	42.74%	6.36%
3. Oversight, security mechanisms and regulations at the national level should be increased for safe, secure and responsible conduct of scientific research.	5.07%	6.64%	10.43%	51.82%	26.52%
4. Scientists have low level of awareness on national civil (including export controls) and penal laws regulating potential misuse of science.	7.14%	13.86%	18.72%	30.31%	17.44%

Contd...

Contd (Table 5.4)

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
5. The use of a "code" that includes the danger of the misuse of science is auspicable for biologists.	3.21%	10.07%	28.51%	45.67%	17.51%
6. Educational and research institutions should include study material on dual-use, biosafety and biosecurity in course work.	2.85%	4.64%	9.29%	50.60%	32.45%
7. Research funders (foundations, governments, …) should have policies regarding funding dual-use research	4.28%	4.71%	15.22%	50.60%	29.45%
8. Scientific journals should have policies regulating the publication of dual-use research.	3.07%	4.07%	12.57%	71.56%	28.66%
9. Misuse of biological knowledge/ techniques is more destructive because there is no defined barrier to control it.	4.07%	5.07%	11.93%	43.96%	35.45%

Q 7. Do you think above mentioned topics are important for life sciences students to be aware of?



Overall, 58.75% of the faculty members considered educating students about dual-use and associated issues as "very important" and 31.66% considered it "important". The respondents were further asked about which issues they thought were the most important, important or somewhat important. The educators regarded bioethics, biosafety, bioweapons, biosecurity, bioterrorism, codes of conduct, biohazards, biological weapons, strong monitoring of research data, dual-use research, proper disposal of contaminants, awareness and practical implementations of these issues as most important for the life sciences students to be aware of. Among these, biosafety (22.83%), biosecurity (12.53%) and

bioethics (10.30%) scored the highest. Similarly, out of the 31.66% educators considered these issues to be "important", highest percent scores were given again to biosafety (17.94%), bioethics (12.82%) and biosecurity (11.28%). Bioterrorism was considered important equal to biosecurity. On the other hand, bioweapons, biosafety and bioterrorism (26% approx. for each) were regarded as somewhat important by 6.64% of the respondents. In addition, 41.18% and 26.97% of the respondents thought that BS/BSc/MSc and M.Phil/MS were the most appropriate levels to teach about dual-use related issues, respectively, whereas only 13.40% opted for PhD, 9.04% for all levels and 8.07% for MBBS. Education and training at the initial stages is important to make students more responsible prior to reaching higher educational level. Moreover, 38.77% expressed their view that such education should be made mandatory for the students while 31.17% and 30.04% were in favor of incorporating dual-use education voluntarily or both, respectively.

The educators were asked to mention the difficulties they think are a big constrain in the way of inserting these topics in curricula. A greater number of respondents mentioned "Lack of awareness" "Lack of training" and "lack of educational materials" as the issues which are creating hurdles in terms of incorporation of dual-use concept in the existing curricula. Some other comments given by a few respondents were as under:

"Lack of educational policies", "Regulatory authorities", "Lack of teaching resources specific to these issues", "Availability of experts", "Role of enforcement/regulatory agencies", "Funding for conducting awareness raising, education and training", "Training of educators", and "Higher authorities".

5.3.4 Comments/Remarks

At the end of the questionnaire, educators were offered with an opportunity to give their comments and suggestions. In their final remarks, a few educators were very appreciative about the survey conducted, saying that:

"This survey is a good effort and practical results must come out of it".

Some individual comments indicated that:

"Awareness on dual-use is a key to responsible conduct of science", and "Students and researchers must have a thorough and up to date knowledge of such issues and should practice in their labs".

Certain problems were pointed out such as:

"Higher education institutions do not have infrastructure to address dual-use risks", and

"In Pakistan, even special BSL labs are not there in many institutions handling dangerous pathogens and no attention paid to the issue of bioterrorism that is the most silent and lethal of all".

Some respondents gave valuable suggestions such as:

"Seminars can prove fruitful to raise awareness on the subject", "Electronic media should play positive role regarding dissemination of biosecurity issues", "Awareness of these issues needed at graduate level so that they are pre-informed before they go for higher level education and carry out ethical research", "Proper implementation of existing biosafety rules for safe use of Biotechnology", "Use of science against peace and solidarity should be discouraged at all levels", "Government should provide resources for conducting awareness raising campaigns", "Bioethical monitoring programs must be practiced at laboratories", "These issues should be addressed in relevant educational departments; clear policies should be made for national universities regarding biosafety, biosecurity, Biodefense",

"HEC should include these topics in their revised curriculum", and "Stricter research codes are needed for institutions like biotechnology and nuclear technology rather than all fields of research".

One negative view also came out from a respondent, i.e., "Keep people unaware of it, it is a new tool of terrorism as spreading information may create problems".

5.4 Conclusions

The current survey provides valuable insight into the levels of awareness, attitudes and opinions of educators about dual-use issues in addition to the information about the current educational offerings in the life sciences discipline. Seeing the responses of the educators about dual-use concerns in the life sciences, it was obvious that the majority was well aware of bioethics, biosafety, biosecurity and other related terms yet these concepts were not taught as separate courses in a majority of Pakistani universities. However, respective terms were included in the curriculum of a few universities. The awareness level of the faculty members about organizations, i.e., national and international regulations, was not adequate. Understanding of dual-use related concept varies based on an individual's scientific field. Participants were found to have some level of knowledge and awareness, but significant gaps were observed in dual-use related information. Most of the participants believed that life sciences research is a dual-use dilemma and steps must be taken to control the potential risks.

The onus of responsible and safe conduct of research ultimately lies on individual scientists (students as well as educators) who must recognize their ethical responsibility (3). The survey urged the need to work on curriculum development and improvement by introducing separate courses for students on dual-use concept or at least their incorporation in the existing syllabi of all the universities offering life sciences courses in Pakistan as well as ensuring the availability of experts and training of the teachers for resource development.

References

1. Fink, G. R., Atlas, R., Barkley, W. E., Collier, R. J., Cozzens, S. E., & Faden, R. (2004). *Biotechnology Research in an age of terrorism: Confronting the Dual-Use Dilemma*. The National Academies Press, Washington, DC, p. 111-126.
2. Shinwari, Z.K., Mancini, G.M., & Pinnard, W.J. (2011). *Introduction to Biorisk Management and Dual-Use in Life Sciences*. The Landau Network Centro-Volta, Italy, 144 pp.
3. Whitman, J. (2010). *When Dual-Use Issues are so Abundant, Why are Dual-Use Dilemmas so Rare?* Research Report for the Wellcome Trust Project on "Building a Sustainable Capacity in Dual-use Bioethics". www.brad.ac.uk/bioethics/media/SSIS/Bioethics/.../monograph-7-JW.pdf.

Chapter 6

Interactive Workshops as Tools for Raising Awareness about Dual-Use Issues

Faouzia Tanveer[1], and Zabta Khan Shinwari[2]

Department of Biotechnology, Quaid-i-Azam University, Islamabad
[1]fouzia.mirza@live.com, [2]shinwari2008@gmail.com

With the emergence of new techniques in life sciences, the need for educating scientists on potential malevolent aspects of their research is critical. Just as information technology revolutionized the world in 20th century, the advances in biotechnology and life sciences are profoundly influencing the 21st century. Biotechnology continues to advance and make progress by leaps and bounds; however, the risks associated with biotechnology demand for building a culture of responsibility from its doers/practitioners (1). This culture is to be adopted at the individual level. Scientists should be the first and foremost units that must exercise responsible conduct of science (2). Educating life scientists about the dual-use concerns of research is a fundamental component of awareness raising campaigns. Institutions imparting higher education can serve the task of training scientists, whether faculty, researchers, students or technical staff, through effective engagement programs (3).

This Chapter reviews awareness campaigns carried out in Pakistan by the Department of Biotechnology, Quaid-i-Azam University (QAU), Islamabad in collaboration with various national and international partners. The main objective was to enhance awareness on dual-use potential of research in life scientists, especially biotechnologists. At least two interactive Workshops were arranged in this regard with young researchers as the main target audience which will be discussed in detail in this chapter. Apart from the Workshops, capacity building, through education of researchers/students of the University (by offering training courses and delivering several talks on dual-use risks associated with emerging technologies at various forums) was the goal for achieving enhanced awareness and promoting education on dual-use issues in Pakistan.

6.1 Gap Analysis

Recognizing the need to assess level of knowledge and attitude of Pakistani life sciences students about bioethics, biosecurity and related issues, a "**Survey on Awareness and Opinions on Biosecurity and Dual-Use among Pakistani Life Sciences Students**" was conducted by QAU during the year 2011, the findings of which were published in the book "**An Introduction to Biorisk Management and Dual-Use in the Life Sciences**" (4). This gap analysis was performed for assessment of the existence of bioethics, biosecurity related knowledge gap in the students. The analysis of the mentioned survey conducted in universities of Pakistan revealed that the level of awareness among the students about dual-use related terms, the concept and the definitions of these terms and knowledge about national and international regulations regarding these issues were not adequate. This lack of awareness existed probably because these issues were not much adequately debated during their university education. Thus, a need was felt to come up with certain programs aimed at engaging the scientific community including the educators as well as the young researchers in order to bridge this knowledge gap.

Moreover, based on the feedback information of the survey, a need for the following aspects was also urged:

- Availability of experts of bioethics/Dual-Use education in universities for educating the students;
- Seminars/workshops be arranged to enhance on-campus awareness;
- Role of media is important for creating/enhancing awareness amongst general public/ communities; and
- Designing courses to raise awareness about biosafety and peaceful conduct of biological research especially at the postgraduate level.

In consideration of this, the Department of Biotechnology, Quaid-i-Azam University, in collaboration with Landau Network Fondazione Volta (LNFV), Inter-Academy Panel (IAP) and Pakistan Academy of Sciences (PAS), conducted Training Workshops on providing bioethics and biosecurity related education and to inculcate the concept of "responsibility in conducting research with dual-use potential" in life scientists. The aim was to fully engage the target audience through the instrument of interactive and participatory learning. Various other sponsors, such as American Academy of Sciences, Higher Education Commission Pakistan, and United Nations Inter-regional Crime and Justice Research Institute, also contributed in successfully conducting these Workshops.

6.2 Workshops' Agenda: Broader Perspective

According to Kruger *et al*. (5), Biosecurity engagement programs based on one-way communication, i.e., solely on information supplies, are not very effective in engaging their target audience. Thus, participatory programs have a good potential for biosecurity engagements. The same can be assumed for awareness raising programs in which participatory and interactive learning approach may prove as an effective tool for engaging the scientific community. Thus, in order to fill the knowledge gap about bioethics, biosecurity and dual-use issues among Pakistani scientists and young researchers, a useful strategy was developed in the form of interactive Workshops (Figure 6.1). The main agenda of these Workshops was to raise awareness about conduct of responsible science among life scientists, especially the young researchers, and to promote dual-use education through a combined approach

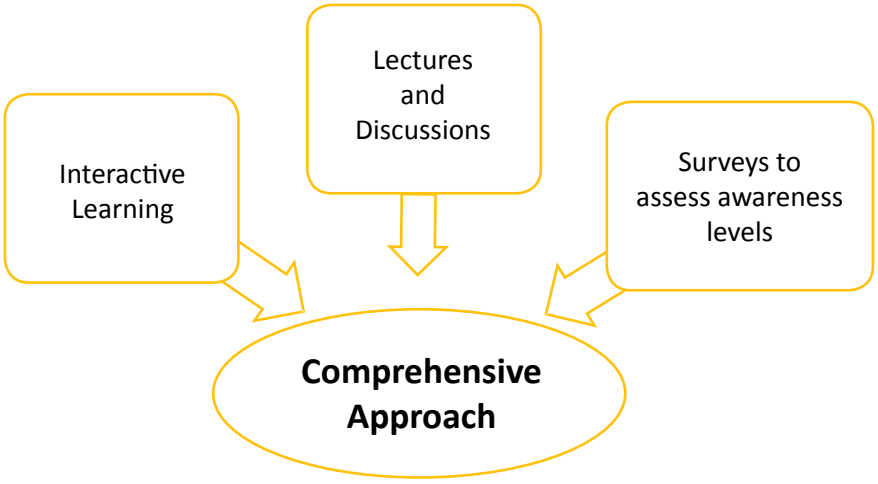


Figure 6.1: An overview of comprehensive agenda of the awareness raising workshops.

of questionnaire survey to assess awareness level, education through lectures delivered by various eminent experts on the subject and group activity encouraging interactive learning. The Workshops were sponsored mainly by the IAP and LNFV (through European Union's Chemical, Biological, Radiological and Nuclear Centers of Excellence) projects awarded to the PAS.

The first Workshop entitled, **"International workshop on Raising Awareness on Dual-Use Concerns in Biotechnology"** was held on 25th March, 2014 at "School of Politics and International Relations, Quaid-i-Azam University, Islamabad. The event was jointly organized by Pakistan Academy of Sciences and Department of Biotechnology, Quaid-i-Azam University. The objective of the Workshop was to identify various social, political, environmental and technical issues related to emerging technologies and put forward recommendations to minimize the hazards produced from these. Moreover, safe and responsible conduct of science was emphasized.

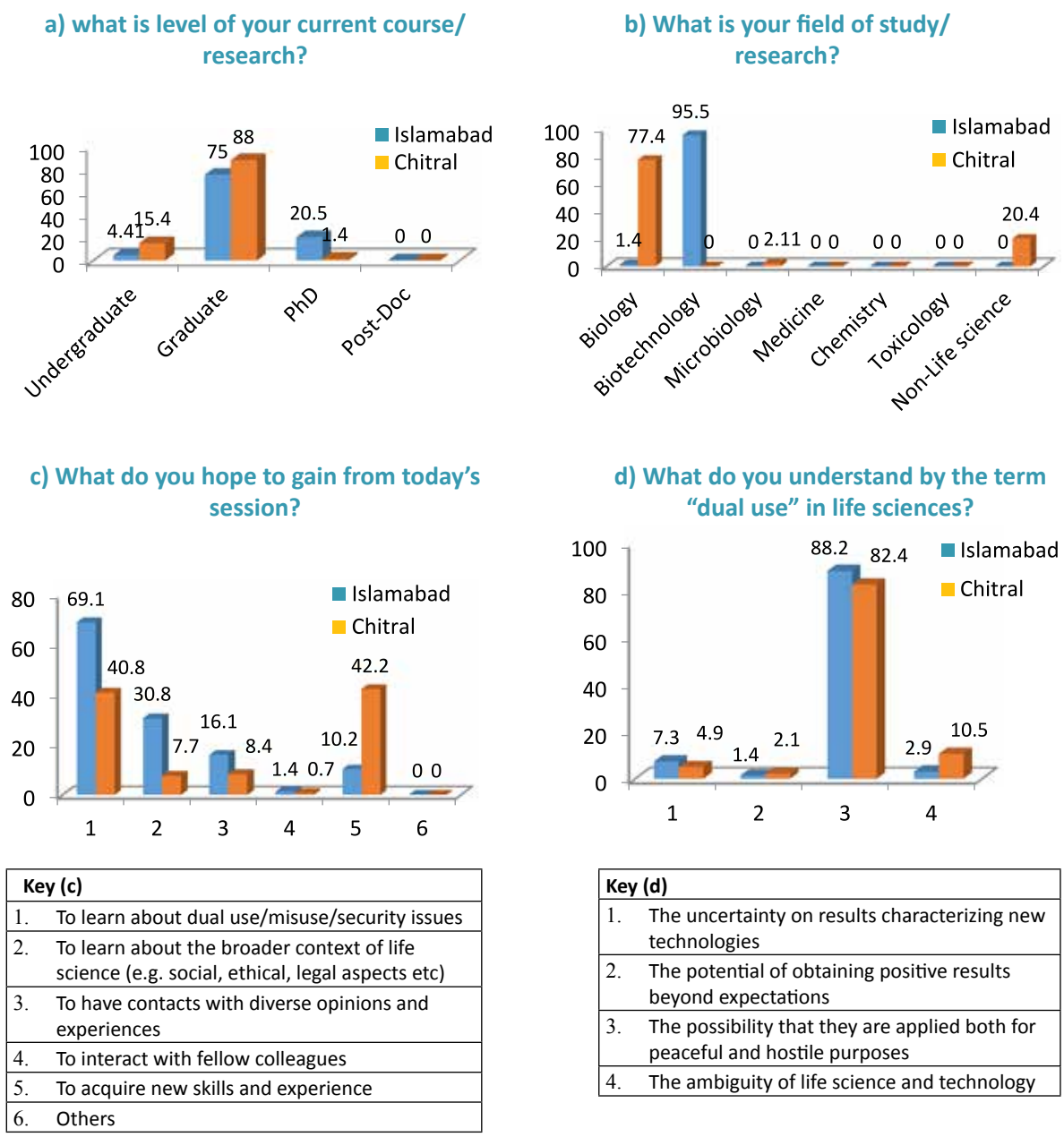
Collaboration is a key to success in terms of the efforts for dissemination of knowledge related to Dual-Use among a wider audience. The Quaid-i-Azam University collaborated with the newly established Shaheed Benazir Bhutto University (SBBU), Shringrial, located in a remote area of Pakistan, and a two-day International Workshop on **"Strengthening the Culture of Responsibility: Dual-Use Research and Bio-security"** was organized at the Auditorium of Abdul Wali Khan University, Chitral in Khyber Pakhtunkhawa on 23-24th May, 2014. This kind of activity was very useful at such a remote area of the country as the prior information about the subject was negligible. The students and researchers were educated about dual-use issues in life sciences and learning through mutual interaction was encouraged which was a new experience for them.

6.2.1 Survey to Assess Awareness Levels

Surveys were conducted to assess the level of awareness in students about biosecurity and bioethics related issues in both the Workshops conducted. Pre- and post-seminar questionnaires were structured so as to analyze both the awareness level and the impact of the Workshops in enhancing knowledge of the participants. A number of students along with faculty members from various universities participated in the two Workshops organized in Islamabad (74 students) and Chitral (148 students). These were helpful in identifying the knowledge gaps in students/young researchers about dual-use concerns so as to devise strategies to address these gaps.

6.2.1.1 Pre-Seminar Questionnaire Results

Majority of the students who participated in the Workshops held at Islamabad and Chitral were of Graduate level (M.Phil.) research scholars with Biotechnology (95.5%) and Biology (Botany, Zoology mainly) (77.4%) as their major field of study, respectively. In Chitral, a few students from Social Sciences Department of the Shaheed Benazir Bhutto University also attended the Workshop; there were certain aspects in the speeches of the national speakers at the event which were useful even to the general audience (such as plagiarism, responsible conduct of research, collaboration, etc). Figure 6.2 and 6.3 illustrate the results of pre-seminar questionnaires. The expectation of majority of the students (69.1% at the Islamabad Workshop) was to learn about dual-use/misuse/security issues from the Workshop. However 30.8% of them also considered that probably ethical, legal and social aspects of life sciences will be discussed in the Workshop. Participants in the Chitral Workshop were of the view that they not only wanted to learn about dual-use issues but also showed a keen desire to acquire new skills and experiences. This could be understood as the Workshop was the first of its kind in such a remote area



Key (c)	
1.	To learn about dual use/misuse/security issues
2.	To learn about the broader context of life science (e.g. social, ethical, legal aspects etc)
3.	To have contacts with diverse opinions and experiences
4.	To interact with fellow colleagues
5.	To acquire new skills and experience
6.	Others

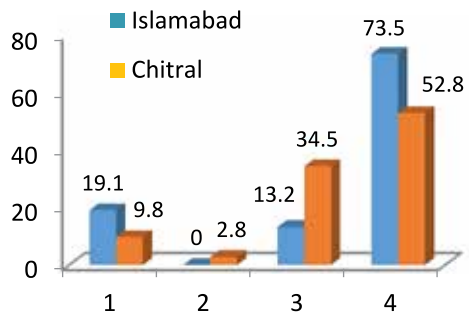
Key (d)	
1.	The uncertainty on results characterizing new technologies
2.	The potential of obtaining positive results beyond expectations
3.	The possibility that they are applied both for peaceful and hostile purposes
4.	The ambiguity of life science and technology

Figure 6.2: Responses to the pre-seminar evaluation questionnaire expressed in percentages (%).

of the country. The students in both the Workshops (more than 80%) seemed well-informed.

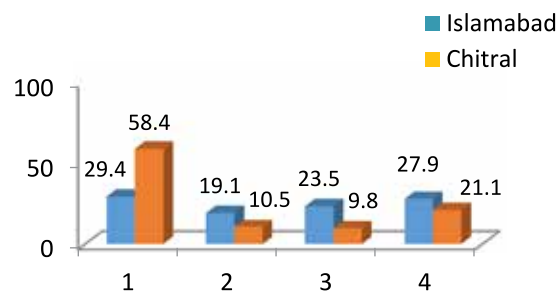
Majority of the students in Islamabad (73.5%) and Chitral (52.8%) Workshops considered laboratory biosafety as "Measures for preventing unintentional exposure to biological agents and toxins or their accidental release". It gave us an idea that knowledge about biosafety does exist among the university students in Pakistan. The responses to the question "Which statement about laboratory biosecurity is not true?" varied among the participants of Islamabad Workshop in which between 20 to 30% of the students responded to each of the options given in the question. So the knowledge about biosecurity was lacking among these students. However, the participants of Chitral Workshop (58.4%)

a) Laboratory biosafety refers to



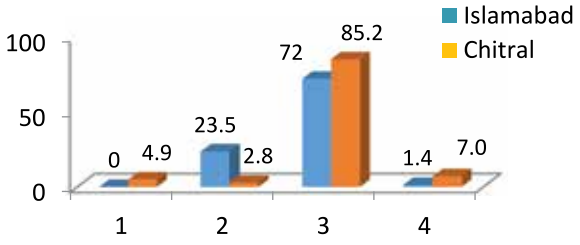
Key (a)	
1.	Measures and policies for preventing the deliberate misuse of pathogens
2.	Measures for preventing theft and loss of pathogens
3.	Measures for preventing the unauthorized access to pathogens and toxins
4.	Measures for preventing the unintentional exposure to biological agents and toxins, or their accidental release

b) Which statement about laboratory biosecurity is not true?



Key (b)	
1.	It comprises policies and practices that require life scientists to consider the ethical, social and legal implications of their work
2.	It comprises measures and policies against the theft and loss of pathogens
3.	It comprises measures and policies against the unauthorized access to pathogens and toxins
4.	It comprises measures and policies that seek to prevent the intentional release of pathogens and toxins

c) Which was the first international treaty to prohibit the use of toxic and biological weapons?



Key (c)	
1.	The Hague Declaration, 1907
2.	Geneva Protocol, 1925
3.	Biological and Toxin Weapons Convention, 1972
4.	Chemical Weapons Convention, 1993

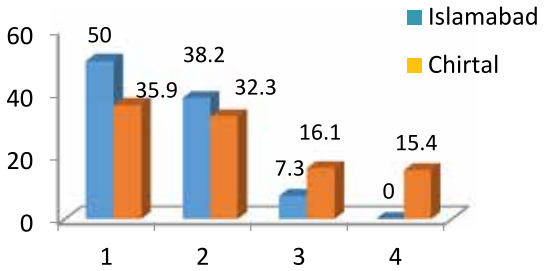
Figure 6.3: Responses to the pre-seminar evaluation questionnaire expressed in percentages (%).

responded that biosecurity does not refer to the policies and practices that require life scientists to consider ethical, social and legal implications of their work. In response to the last question which was posed to assess the knowledge of students about the first international treaty concerning the toxic and biological weapons, more than 70% of the participants of both the Workshops regarded Biological and Toxin Weapons Convention (1972) as the first international treaty.

6.2.1.2 Post-Seminar Questionnaire Results

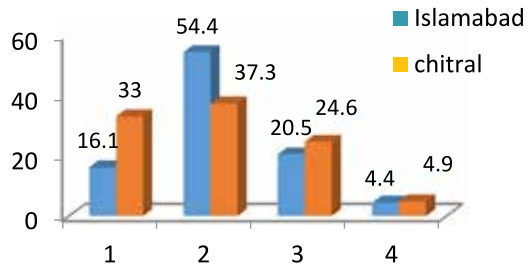
Half of the respondents (50%) at the Islamabad Workshop said they had prior information about the topics discussed in the Workshop (may be because a number of students were taking a relevant course in "Dual-Use Research of Concern") and so they could easily follow the Workshop, yet about 30%

a) Was your previous knowledge sufficient to follow the seminar?



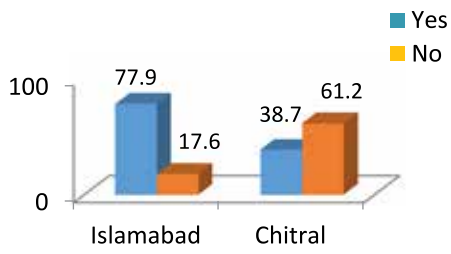
Key (a)	
1.	Yes
2.	Yes, even if having further information would have been helpful
3.	No, but I could follow the seminar easily anyway
4.	No, and this proved difficult

b) Were the topics addressed discussed in other courses?

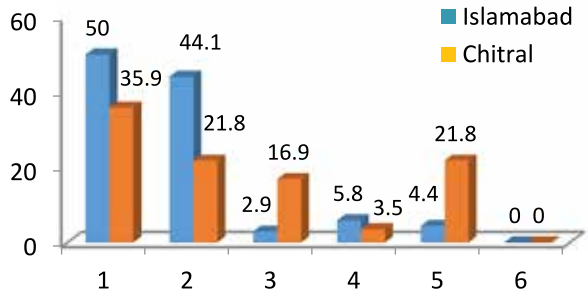


Key (b)	
1.	No
2.	Yes, but it was useful to discuss them today
3.	Yes, a few
4.	Yes, most of them

c) Had you any prior knowledge about the potential "hostile misuse" of life sciences?



d) What did you gain from today's session?

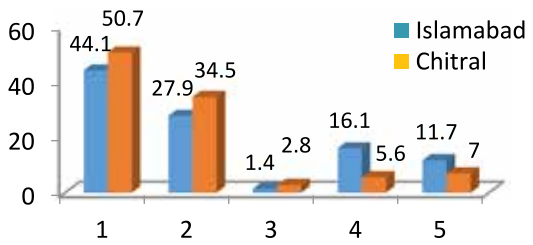


Key (d)	
1.	I learnt about dual use/misuse/security issues
2.	I learnt about the broader context of life science (e.g. social, ethical, legal aspects, etc)
3.	I learnt about diverse opinions and experiences
4.	I interacted with fellow colleagues
5.	I acquired new skills and experience
6.	Others

Figure 6.4: Responses to the post-seminar evaluation questionnaire expressed in percentages (%).

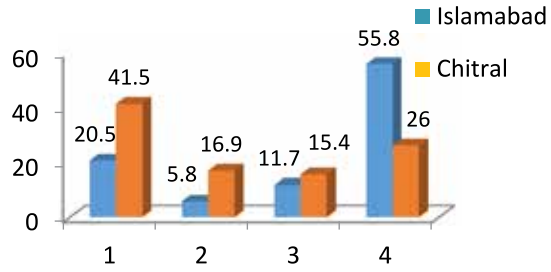
believed that having further information was useful to them. In the Chitral Workshop, only 30-35% of the participants responded that they had information about dual-use/misuse/biosecurity issues, yet the current Workshop proved to be very useful for enhancing their further knowledge. They were also asked whether these topics were discussed during their course work, and only 37.3% in Chitral and 54.4% in Islamabad Workshop responded positively to this question. However, they said it was still useful to discuss these topics in the Workshop. When the participants were asked about their information on hostile misuse of life sciences research, 77.9% and 61.2% knew in advance about its

a) What are the important things to remember about dual use/misuse?



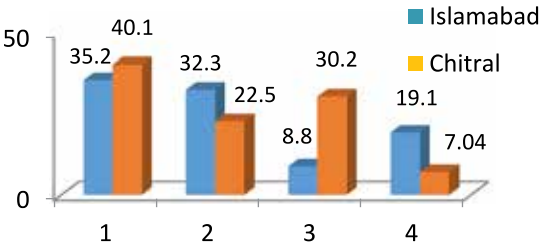
Key (a)	
1.	Life scientists should be aware of the social, ethic and legal implications of their work
2.	Life scientists should be aware both of the national and international regulations relevant to their work
3.	Cost-benefit analysis is an essential element in mitigating the risks associated to life science research of concern
4.	There are potential risks and impacts on society to consider
5.	It is important to balance freedom of research and regulation of science

b) Laboratory biosafety refers to



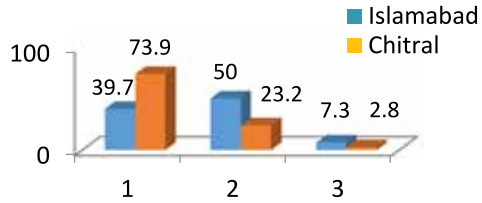
Key (b)	
1.	Measures and policies for preventing the deliberate misuse of pathogens
2.	Measures for preventing theft and loss of pathogens
3.	Measures for preventing the unauthorized access to pathogens and toxins
4.	Measures for preventing the unintentional exposure to biological agents and toxins, or their accidental release

c) Which statement about laboratory biosecuirty is not true?



Key (c)	
1.	It comprises policies and practices that require life scientists to consider the ethical, social and legal implications of their work
2.	It comprises measures and policies against the theft and loss of pathogens
3.	It comprises measures and policies against the unauthorized access to pathogens and toxins
4.	It comprises measures and policies that seek to prevent the intentional release of pathogens and toxins

d) What tools do you have available to acquire new information and enrich your knowledge about biosafety/biosecurity issues?



Key (d)	
1.	University library
2.	Web Sites
3.	E-learning web platforms

Figure 6.5: Responses to the post-seminar evaluation questionnaire expressed in percentages (%).

potential misuse in Islamabad and Chitral, respectively. Figure 6.4 and Figure 6.5 illustrate the results of post-seminar questionnaires.

Half of the participants in the Islamabad Workshop were of the view that they had learnt about dual-

use/ misuse of research while 44% got information regarding broader context of life sciences, i.e., social, legal and ethical aspects of research. In Chitral, however, more number of students (35.9%) gained knowledge about dual-use/misuse issues, some (21.8%) learned about social, legal, ethical aspects of scientific research and still a few more said they also acquired new skills and experiences. Between 40 to 50% of the students in both the Workshops expressed their views that life scientists should be aware of the ethical, social and legal implications of their work and should have information about national and international regulations regarding it. Majority of the students (55.8%) in the Islamabad Workshop agreed that laboratory biosafety means "Measures for preventing the unintentional exposure to biological agents and toxins, or their accidental release". The responses were similar to the results of the pre-seminar questionnaires. In Chitral, however, a shift in the response was observed where 41.5% respondents referred to biosafety as "Measures and policies for preventing the deliberate misuse of pathogens" in addition to 26% who also considered it as a measure to prevent unintentional exposure or the accidental release of the biological agents.

Table 6.1 UNICRI part of the questionnaire.

Question	% Responses	
	Islamabad	Chitral
I was well **informed** about the objectives of this Workshop		
1 = strongly agree	45.5	50.70
2 = agree	50	33.09
3 = neither agree nor disagree	0	10.56
4 = disagree	1.4	1.4
5 = strongly disagree	0	2.81
9 = N/A	0	1.4
This Workshop lived up to my **expectations**		
1 = strongly agree	35.29	31.69
2 = agree	61.76	54.92
3 = neither agree nor disagree	0	8.45
4 = disagree	1.4	2.81
5 = strongly disagree	0	0
9 = N/A	0	2.11
The Workshop content is **relevant** to my job		
1 = strongly agree	41.17	37.32
2 = agree	42.64	33.09
3 = neither agree nor disagree	8.8	5.63
4 = disagree	0	19.71
5 = strongly disagree	0	1.4
9 = N/A	4.4	2.81

Continued...

Table 6.1 (Continued)

Question	% Responses	
	Islamabad	Chitral
In my view, the **objectives** of the Workshop were achieved		
1 = strongly agree	36.76	41.54
2 = agree	57.35	38.73
3 = neither agree nor disagree	2.94	7.04
4 = disagree	0	4.22
5 = strongly disagree	0	0.70
9 = N/A	0	0.70
The overall **quality** of the Workshop was high		
1 = strongly agree	36.76	37.32
2 = agree	55.8	54.92
3 = neither agree nor disagree	4.4	6.33
4 = disagree	1.4	1.4
5 = strongly disagree	0	0
9 = N/A	1.4	0
The Workshop presented information **clearly**		
1 = strongly agree	35.29	35.21
2 = agree	57.35	51.40
3 = neither agree nor disagree	2.94	3.52
4 = disagree	0	8.45
5 = strongly disagree	0	0.7
9 = N/A	0	0.7
The Workshop allowed me to **participate and interact** with others		
1 = strongly agree	38.2	67.60
2 = agree	57.35	29.57
3 = neither agree nor disagree	2.94	1.4
4 = disagree	0	0
5 = strongly disagree	0	0
9 = N/A	0	1.4
Potential **language limitations** were well taken into account and adequately managed at the Workshop		
1 = strongly agree	27.94	19.71
2 = agree	66.17	68.30
3 = neither agree nor disagree	1.4	4.22
4 = disagree	1.4	4.22
5 = strongly disagree	0	0.7
9 = N/A	0	2.11

Moreover, responses of the students varied about the definition of "Biosecurity" in both the Workshops with most of them considering it as policy and practice that requires life scientists to consider the ethical, social and legal implications of their work. It demonstrates that they probably lacked information about its concept. It is also possible that the varied response came out of the fact that biosecurity is a much broader concept and can be viewed in a number of contexts as according to WHO (6). Majority of the students in the Islamabad Workshop said that they learned about biosafety/biosecurity issues through websites such as HEC digital library, NCBI, Pubmed, NSAAB and Science Direct as mentioned by them in response to the question posed. Most of the students in the Chitral Workshop learned about biosafety/biosecurity issues from their university library or their course books, however, a few of them mentioned using the search engine; Google.

A part of the questionnaire also aimed at judging the opinions and views of participants about the effectiveness of the seminar in presenting DURC related information (Table 6.1). The students agreed that the Workshop was of high quality, achieved its objectives and presented information clearly. Moreover, they agreed that the content presented in the Workshop was relevant to them and lived up to their expectations. The Workshop not only gave them a platform to enhance their skills but also encouraged mutual interaction.

6.2.2 Interactive Learning

Active learning encourages students to engage themselves in a practice of metacognition, i.e., ability of self-assessment, evaluation and problem solving. This approach coupled with communicative strategies can be implemented in teaching young scientists and students about dual-use issues and responsible science conduct (3). Thus, active involvement of the students was ensured during the Workshops. The students were divided into groups and given the task to design their own posters on the subjects related to dual-use/biosecurity through mutual cooperation and group discussions. They were also given the chance to present their posters in the Workshop. The groups were formed on the following themes:

- Science & Biosecurity
- Emerging Technologies & dual-use Applications
- Falsification, Fabrication & Plagiarism
- Right of Publications
- Collaborative Science
- Mentor-mentee Relationship
- Access & Benefit Sharing
- Research on Infectious diseases: Prospects & Challenges

Among participants of the Workshop held in Islamabad, a majority of students (mainly of M.Phil) enrolled in a course "Bioethics and Dual-Use Education" taught at the Department of Biotechnology, QAU, presented their posters which were designed after multiple sessions and group activities done in the classroom. Thus, concept of interactive and participatory learning has been incorporated in the curriculum taught at the university.

6.2.3 Lectures and Discussions

Another important instrument of enhancing DURC related awareness in the scientific community is provision of information and training on the subject. During the Workshops, various scientists working

on dual-use/misuse awareness raising campaigns delivered their talks on a range of subjects related to dual-use issues of life sciences, specifically biotechnological research. Following were the main focal points of their talk:

- Dual-Use/ misuse of the scientific research;
- Biosafety and biosecurity issues and the necessary steps needed to be taken at individual, social and governmental level;

Figure 6.6: Participants of the Islamabad Workshop.

Figure 6.7: Prof. Dr. Zabta K. Shinwari delivering his talk during the Islamabad Workshop. Chairman of Higher Education Commission, Dr. Mukhtar Ahmad, chaired the session.

Figure 6.8: Students presenting their posters in the Islamabad Workshop.

Figure 6.9: Females participants of the Chitral Workshop.

Figure 6.10: Dr. Anwar Nasim talking about "Role of youth as responsible scientists".

Figure 6.11: Group activity at the Chitral Workshop.

Figure 6.12: A poster on "Research misconduct".

- Stress on making the conduct of science more responsible;
- Education about the use of emerging technologies raising many dual-use concerns such as creation of new pathogens or re-creation of already eradicated pathogens in the lab which can be used as weapons or inadvertently can harm life and the environment;
- Information to the participants about codes of conduct in science and role of institutions in implementing an organized system/governing bodies of biosafety and biosecurity; and
- The concept of plagiarism, fabrication and falsification in research.

  During this session, the queries and questions by the students were encouraged and their views and suggestions were appreciated.

6.3 Important Outcomes

Overall, the Workshops facilitated in enhancing knowledge about issues such as research misconduct and compliance, threats to humans and environment from deadly pathogens created through emerging technologies such as genetic engineering, synthetic biology, codes of conduct, etc. The participants were trained to avoid unintentional/ accidental or intentional misconduct of research. The interactive session and the poster presentations by the students provided an opportunity for them to share their ideas about different dual-use issues.

6.4 Feedback from Students/Young Researchers

Majority of the students gave positive feedback about outcome of the Workshops. They were of the view that interactive session and the group activity of the students was the most interesting part as it fully engaged all the participants. A few students mentioned in their comments that their knowledge and awareness about bioethics, biosecurity issues was increased after attending the Workshop. Participants of the Chitral Workshop appreciated the motivating talks of the guest speakers and expressed their interest in having multiple sessions on dual-use concerns in order to convey further information as their awareness levels about the subject were low as compared to students who attended the Workshop in Islamabad. Some participants suggested that a proper discussion forum must be provided in such Workshops where innovative ideas can be shared between the dual-use experts and new researchers (students) regarding policy making in biosecurity/biosafety related issues. Some of the students of remote areas (i.e., Chitral and its suburbs) who attended the Workshop faced a little problem in understanding the questionnaires in English.

In addition to interactive Workshops, Department of Biotechnology, Quaid-i-Azam University has also been offering a course on "Bioethics and Dual-Use Education" as a core subject at postgraduate level for the last few years (Figure 6.13). Human resource development through education and training of young scientists about the responsible and quality conduct of science is necessary. In turn these

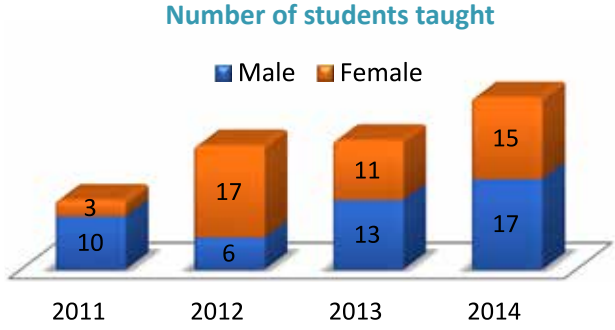


Figure 6.13: Number of students enrolled in the course on "Bioethics and Dual-Use Education" (Years: 2011-2014).

trained scientists can serve as an impetus in spreading awareness of this view further. National and international conferences offer a good platform for spreading awareness about dual-use concerns. Dr. Zabta Khan Shinwari has raised his voice on dual-use issues in life sciences and biotechnology at various forums in Pakistan. The most recent activities include a lecture on synthetic biology in relation to infectious diseases and dual-use issues at the Pakistan Academy of Sciences on Feb. 13, 2014, and by participation in 4th International and 13th National Conference of Botany on Aug. 27-30, 2014 at Shaheed Benazir Bhutto University-Sheringal, Dir (Khyber Pakhtunkhawa) where he presented a talk on "Why Discuss Research Integrity?" and by delivering a talk on "Emerging pathogens and dual-use issues" at International Conference on Emerging Trends in Life Sciences for Sustainable Development on 9-11th October, 2014 organized by the Biological Sciences Department of Forman Christian College, Lahore. Moreover, a group of young scientists has been developed for working on DURC projects in Pakistan which is a valuable human resource to take forward the mission of raising awareness and education of dual-use concerns in life sciences research.

All these efforts aimed at educating the life scientists to make them understand their responsibilities about safe and ethical conduct of research. Awareness raising programs such as seminars, symposia and workshops provide a good platform for training students as well as faculty of the institutions of higher education. Involvement of these institutions themselves in developing and implementing awareness raising programs and course development on dual-use education is a must. Education in Pakistani universities is mostly lecture-based, so learning through mutual interchange of ideas and participation of students is a good way. It can be inferred from the analysis of interactive workshops that incorporation of participatory learning in the awareness raising programs proved effective in achieving the goal of imparting education on DURC.

References

1. Mancini, G., Revill, R., Martellini, M., & Dando, M. (2008). *Fostering the Biosecurity Norm: Biosecurity Education for the Next Generation of Life Scientists*. Landau Network-Centro Volta, Como, Italy. Available at: http://www.centrovolta.it/landau/content/binary/LNCV.
2. Terence, T.T., Azhar, A., Khan, M.A., Malik, K., & Nasim, A. (2012). Safety, security, and ethics in the biological realm are a multi-disciplinary challenge-that begins and ends with the individual. *Applied Biosafety, 17 (3),* Guest Editorial.
3. National Research Council (2011). Research in the Life Sciences with dual-use Potential: An International Faculty Development Project on Education about the Responsible Conduct of Science. *The National Academic Press, Washington, DC.*
4. Shinwari, Z.K., Mancini, G.M., & Pinnard, W.J. (2011). *Introduction to Biorisk Management and Dual-Use in Life Sciences*. Landau Network Centro-Volta, Italy, 144 pp.
5. Kruger, H., Thompson, L., Clarke, R., Stenekes, N., & Carr, A. (2009). *Engaging in Biosecurity: Gap Analysis*. Bureau of Rural Sciences, Australian Government, Canberra, 39.
6. World Health Organization (2006). *Biorisk Management: Laboratory Biosecurity Guidance*. Available via http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

Department of Biotechnology
Quaid-i-Azam University
Islamabad, Pakistan
Tel: +92-51-906 44187
E-mail: shinwari2008@gmail.com
Website: www.molecular-systematics.org

Pakistan Academy of Sciences
3-Constitution Avenue, G-5/2, Islamabad, Pakistan
Email: sec.gen@paspk.org, editor@paspk.org
Tel: +92-51-920 4843, 920 7140
Website: www.paspk.org